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IN THE

Supreme Court of the United States

APOTEX USA, INC.,

Petitioner,

v.

MERCK PHARMACEUTICAL CO.,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Merck has made VASOTEC® since 1983 using a chemical reaction that it kept secret. Merck asserted that Apotex's generic drug (with the same active ingredient that Merck claimed was in its drug) infringed a Canadian patent. Apotex argued that Merck's patent was invalid because it did not disclose the chemical reaction that Merck was keeping secret. Merck ***denied*** that the chemical reaction occurred and ***prevailed*** on that theory in the Canadian suit. During that suit, Apotex discovered a previously undisclosed process to get that chemical reaction. Apotex patented its new process in the United States then sued Merck for infringement. Merck, however, then asserted that it ***did*** make its product using that chemical reaction (which it had ***denied*** before), and that it had used Apotex's process since 1983. Merck moved for summary judgment of invalidity — relying on materials from the Canadian suit as clear and convincing evidence to negate its suppression and concealment, even though Merck had convinced that Canadian court that no reaction occurred. Merck received summary judgment despite its inconsistent and hypocritical positions, amounting to a fraud on the courts and patent system that may well amount to billions of dollars. The Federal Circuit's affirmance is a radical departure from the usual course of judicial proceedings. The district court nullified Apotex's federal property right in its U.S. patent, without trial, despite evidence of Merck's suppression and concealment including expert testimony, documents Merck submitted to the FDA, and Merck's own prior conduct.

The question presented, therefore, is:

Whether summary judgment extinguishing a patentee's federal property right is properly granted in favor of a party

that bears the burden of proving by clear and convincing evidence that it did not suppress or conceal an invention under 35 U.S.C. §§ 102(g), 282, based on disclosures in a foreign court allegedly negating suppression and concealment, when:

(1) its initial secrecy created a presumption that it suppressed and concealed the invention;

(2) it ***never*** disclosed the invention in the United States, but instead the only disclosures allegedly negating suppression and concealment were outside the United States;

(3) it argued in a foreign court that it did not use the invention and ***prevailed*** in that argument when all of the disclosures allegedly negating suppression and concealment were before that foreign court;

(4) its own paid expert testified in that foreign court that those disclosures did ***not*** show use of the invention;

(5) it never identified the alleged prior inventor as required by statute, and

(6) it offered ***no*** evidence that its alleged disclosures outside the U.S. were sufficient for the public in the United States to gain knowledge of the invention to insure its preservation in the public domain; and

(7) an internal document establishes its motive to suppress and conceal the invention by admitting that if the truth got out it might affect worldwide registration and existing approved labelling.

CORPORATE DISCLOSURE STATEMENT

The petitioner Apotex USA, Inc., has no parent corporations and no publicly held company owns more than 10% of its stock.

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Apotex USA, Inc., ("Apotex") respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit in this case.

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. A, 1a-17a) is reported at 254 F.3d 1031 (Fed. Cir. 2001). The opinions of the trial court on summary judgment (Pet. App. B, 18a-38a), and denying reconsideration (Pet. App. C, 39a-45a), are unreported.

STATEMENT OF JURISDICTION

The Federal Circuit entered the judgment of which Apotex seeks review on June 8, 2001. (Pet. App. A at 1a.) It denied rehearing on August 2, 2001. (Pet. App. D at 46a-47a.) Apotex invokes the jurisdiction of this court under 28 U.S.C. § 1254(1) (1994).

CONSTITUTIONAL AND STATUTORY PROVISIONS AT ISSUE

The Constitution gives Congress the power:

> To promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries

U.S. Const., art. I, § 8, cl. 8.

The Bill of Rights provides:

> In Suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved, and no fact tried by a jury, shall be otherwise reexamined in any Court of the United States, than according to the rules of the common law.

U.S. Const. amend. VII:

The United States Code in Title 35 — Patents, Chapter 100 — Patentability of Inventions, provides that a person is entitled to a patent unless:

> (g)(2) before such person's invention thereof, the invention was made in this country by another inventor ***who had not abandoned, suppressed, or concealed it.***

35 U.S.C. § 102(g) (1994 Supp. V) (emphasis added).

The United States Code in Title 35 — Patents, Chapter 29 — Remedies for the Infringement of Patent, and Other Actions, provides:

> In actions involving the validity or infringement of a patent ***the party asserting invalidity or noninfringement shall give notice*** in the pleadings or otherwise in writing to the adverse party at least thirty days before the trial, of the country, number, date, and name of the patentee of any patent, the title, date, and page numbers of any publication to be relied upon as

> anticipation of the patent in suit or, except in actions in the United States Court of Federal Claims, as showing the state of the art, and ***the name and address of any person who may be relied upon as the prior inventor or as having prior knowledge of or as having previously used or offered for sale the invention of the patent in suit.*** In the absence of such notice proof of the said matters may not be made at the trial except on such terms as the court requires.

35 U.S.C. § 282 (1994 Supp. V) (emphasis added).

STATEMENT OF THE CASE

Since the 1980's, Merck has made a hypertension drug under the brand name VASOTEC®. (Pet. App. at 3a.) Merck's labels state that the tablets contain enalapril maleate as its active ingredient. Merck owned a patent claiming enalapril maleate and some other enalapril compounds and uses. Merck's patent stated that a drug containing enalapril maleate could be made by using commonly known adjuvants (L22), which are pharmacological agents added to a drug to increase or aid its effect.

Enalapril maleate is made with maleic acid and is itself slightly acidic. (*See* L2, L22.) It can react with a base such as sodium bicarbonate, which reaction converts the enalapril ***maleate*** to enalapril ***sodium*** and other byproducts. (L2.) The acid and base do not react when mixed in their dry form. Another, older patent taught that the acid enalapril maleate and base sodium bicarbonate would react to yield enalapril sodium (and other products), if mixed with enough water to

make a clear solution. (L2.) A process that requires making a clear solution, however, is undesirable for manufacturing. (L2.)

In the 1980s, a Canadian company, Apotex, Inc. (an affiliate of the petitioner Apotex USA Inc.), tried to make a generic equivalent of VASOTEC®. *Merck & Co., Inc. v. Apotex, Inc.*, 59 C.P.R. (3d) 133 (1994), *reprinted at* L10-L63. Enalapril maleate, however, proved unacceptably unstable, even when combined with common adjuvants. (L2, L58, L91.) Tests by Apotex, Inc., suggested that VASOTEC® might include a sodium compound. (L91.) Apotex, Inc., tried mixing enalapril maleate with sodium bicarbonate (in dry form ***without*** producing an acid-base reaction), but found that the result was even ***less*** stable than enalapril maleate by itself. (L92.) Apotex, Inc., avoided the acid-base reaction because VASOTEC®'s labeling and other sources listed its active ingredient as enalapril ***maleate***, not enalapril ***sodium***. In early 1991, Apotex, Inc., developed an acceptable generic drug that did have enalapril maleate (***not*** enalapril sodium) as its active ingredient, but only after the most difficult product development in its experience. (L58.)

After Merck's Canadian patent on enalapril maleate issued, Merck sued Apotex, Inc., for patent infringement. (L10-L63.) In that litigation, Apotex, Inc., tried to prove Merck's patent invalid.[1] Apotex, Inc., argued that (contrary to statements in Merck's Canadian patent, and unlike the

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1. That suit also included issues of Canadian law not relevant here, such as whether Apotex, Inc., could use product it purchased in Canada before Merck's patent issued.

pharmaceutical Apotex sold) Merck did ***not*** make VASOTEC® by combining the active ingredient enalapril maleate with an adjuvant or a "stabalizer." (L58.) Apotex argued that instead a chemical reaction probably occurred that might itself be inventive, but which was not disclosed in Merck's patent as required by Canadian patent law. (L58.)

Documents Merck produced during the Canadian litigation indicated that VASOTEC® contained sodium bicarbonate or sodium carbonate. From 1983 (when Merck first began making VASOTEC®) until 1988, Merck did not disclose but instead concealed the fact that sodium bicarbonate had anything to do with VASOTEC®. (Pet. App. at 13a-14a.)

Even when Merck eventually disclosed that VASOTEC® included sodium bicarbonate, its disclosures did not negate its earlier suppression and concealment because they were misleading about ***how*** sodium bicarbonate was involved. Those disclosures suggested that sodium bicarbonate was among the final contents of VASOTEC®, ***not*** that it was a starting ingredient used in a chemical reaction to yield a ***different*** product having an active ingredient of enalapril ***sodium*** instead of enalapril ***maleate***. Merck's alleged disclosures included a 1988 French-language publication *Dictionnairre Vidal*, a 1992 Canadian product monograph, and a silent video and narration presented only in the Canadian courtroom where Merck was suing Apotex, Inc. ***None of those disclosures showed an acid-base chemical reaction.*** In the Canadian litigation, Merck even ***denied*** that any reaction occurred.

When Dr. Sherman (the president of Apotex and the chairman of Apotex, Inc.) learned that Merck did include sodium bicarbonate in VASOTEC®, he already knew from the previous experiments at Apotex, Inc., that if the sodium bicarbonate were mixed with the enalapril maleate but the two did not react, then the resulting pharmaceutical would not be stable. (L93-L94.) He therefore thought that an acid-based reaction might be occurring. Dr. Sherman then authorized experiments during the Canadian litigation on reacting enalapril maleate with sodium bicarbonate.

During those experiments, Dr. Sherman discovered that one could react sodium bicarbonate and enalapril maleate in a wet mass, ***without forming a clear solution***. The absence of a clear solution distinguished this process from the prior art. The exact amount of water was critical. Too little water would not produce the desired chemical reaction. Too much water would make a clear solution, as shown in the prior art.

Merck, however, denied that any reaction occurred. It concealed the fact that the reaction occurred even from its own expert in the Canadian litigation, Dr. Schwartz. Dr. Schwartz was the ***only*** U.S. citizen shown to have any knowledge of the Canadian litigation. (*See* Pet. App. at 45a n.1.) The information then available to Dr. Schwartz included the 1988 *Dictionnairre Vidal*, the 1992 Canadian product monograph, the mock-up video and narration by Brian McLeod (an officer of Merck), and a declaration filed by Dr. Sherman. He testified as an expert on pharmaceuticals that ***he could not tell from that information that any reaction occurred.*** Merck ***prevailed*** in its position in that litigation, and the Canadian court concluded that one could not tell that any such reaction was really occurring. (L58.)

Dr. Sherman filed a patent application in the United States that resulted in U.S. Patent Nos. 5,573,780 (issued Nov. 12, 1996) ("the '780 patent") (L1-L5) and 5,690,962 (issued Nov. 25, 1997) ("the '962 patent") (L6-L9). At the time Dr. Sherman filed those applications, Merck had ***denied*** that it used the process he claimed and the Canadian court had ***agreed*** with Merck. Believing that Merck might have used Dr. Sherman's process after the Canadian litigation, Apotex commenced the instant civil action for patent infringement against Merck. Jurisdiction was proper in the United States District Court under 28 U.S.C. § 1338 (1994 Supp. V).

In this litigation, however, Merck reversed its position 180° from the argument on which it had prevailed in Canada. Now Merck argued that it had really invented Dr. Sherman's process, and had been using it since 1983. In combining this new argument with its previous argument on which it had prevailed, Merck tries to ***suck*** and to ***blow*** at the same time. The Federal Circuit (in the decision for which certiorari is here sought) agreed that Merck's failure to disclose the inclusion of sodium bicarbonate before 1988 was by itself enough "to create a genuine issue of material fact that Merck suppressed and concealed" its alleged prior invention. (Pet. App. at 13a-14a.)

Merck, however, argues (and the courts below agreed) that its disclosures from 1988 through and including the 1994 Canadian litigation negated its earlier suppression and concealment. It argues that those disclosures negated suppression and concealment by revealing its starting ingredients and its process. As will be shown below, however, Apotex submitted expert declarations that explained that in this art one would understand all of Merck's disclosures up

until 1994 as listing not starting ingredients in a chemical reaction, but instead the ***final contents of its drug***.

Merck's argument of prior inventorship invalidating the patent is an affirmative defense in a patent infringement action. It was Merck's burden to prove this affirmative defense, and the standard of proof was clear and convincing evidence. 35 U.S.C. § 282 (1994 Supp. V). Merck was also obliged under the statute to identify the alleged prior inventor by name and address. *Id.* Moreover, Merck was required to prove by clear and convincing evidence that no one suppressed or concealed its alleged prior invention in the United States.

Merck moved for summary judgment on its affirmative defense. (Pet. App. at 18a–38a.) As evidence that it did not suppress or conceal the process Dr. Sherman later invented, Merck pointed to its sales of VASOTEC®, the 1988 *Dictionnairre Vidal*, the 1992 Canadian product monograph, and the 1994 mock-up video and accompanying testimony by Brian McLeod. (Pet. App. at 16a; Pet. App. at 35a.) The issue, therefore, was whether Merck's later disclosures were sufficient to negate its earlier suppression and concealment. Apotex opposed summary judgment with expert declarations showing that Merck's alleged disclosures did ***not*** negate Merck's earlier suppression and concealment, but were instead misleading in their own right and thus only further suppressed and concealed the invention.

Merck relied in part on its prior sales of VASOTEC®. The labels on VASOTEC® list the active ingredient as enalapril maleate. Nothing on the label indicates that the active ingredient is really enalapril sodium. Nothing on the label indicates that enalapril maleate is really an initial

ingredient in a process to produce VASOTEC® tablets. The label does not list water, which would be a necessary ingredient in a reaction to produce enalapril maleate but is not an ingredient of the final contents. Instead, the label lists enalapril maleate as the active ingredient in the final contents and does ***not*** identify enalapril sodium as an ingredient in the final contents.

The first alleged disclosure that sodium bicarbonate had anything to do with VASOTEC® was in 1988 in the French-language publication *Dictionnairre Vidal*, some five years after Merck allegedly began using the process. (Pet. App. at 15a.) Merck listed sodium bicarbonate among the contents of RENITEC, the brand name it used in France for VASOTEC®. However, nothing in that entry for RENITEC suggested that these were not in fact the final contents but were instead the starting ingredients for a chemical reaction. The entry omits water, which would be a necessary ingredient in the reaction but is not among the final contents. The entry lists enalapril maleate as the active ingredient in the final contents, and does ***not*** identify enalapril sodium as an ingredient in the final contents.

Starting in 1992, Merck distributed a product monograph in Canada that listed sodium bicarbonate among the contents of VASOTEC®. (*See* Pet. App. at 16a, 45a.) Like the product label and the entry in the 1988 *Dictionnairre Vidal*, nothing in the monograph identifies enalapril maleate and sodium bicarbonate as starting ingredients for a reaction. Instead, the product monograph lists these compounds in the contents of the final product. The product monograph does not list water, which would be a necessary ingredient in the reaction but is not an ingredient of the final contents. The product monograph lists enalapril maleate as the active ingredient in

the final contents, and does ***not*** identify enalapril sodium as an ingredient in the final contents.

During the Canadian litigation in 1994, Brian McLeod, an officer of Merck, narrated a silent video that purported to depict the manufacture of VASOTEC®. Merck admitted that in its video it did ***not*** use the real ingredients from its process, even though there was no reason to substitute ***fake*** ingredients. Apotex filed expert affidavits explaining that the video and the accompanying narration did not negate Merck's prior suppression and concealment. The silent video concealed the use of sodium bicarbonate. It concealed any chemical reaction between the undisclosed sodium bicarbonate and enalapril maleate. The silent video with McLeod's narration did show that Merck used some water and produced a wet mass, but did ***not*** specify how much water Merck used. Nothing in those disclosures identified sodium bicarbonate or where in the process Merck allegedly used that ingredient. Those disclosures also concealed the fact that one of the products of the chemical reaction was enalapril sodium. (L82-L89.)

Apotex offered evidence that the mock-up video Merck used in the 1994 Canadian trial suppressed and concealed the truth — the chemical reaction to convert enalapril maleate to enalapril sodium without making a clear solution enalapril maleate of enalapril sodium and maleic acid sodium salt in water. McLeod admitted "what you are looking at is in fact not really enalapril or the ingredients. We choose not to use the active ingredients in this particular production. . . ." He admitted that Merck made the decision not to identify the actual ingredients in its process during the narration, even though "there was no reason not to." Merck did not tell the Canadian Court, or even its own testifying expert, Dr. Schwartz, that any such reaction occurred.

Dr. Sherman submitted a declaration establishing that McLeod did not indicate whether or not anything dissolved in the water or what the other ingredients were. (L104.) McLeod testified to the presence of a stabilizer, but made no mention of any ***reaction***. (L104.) McLeod thus indicated that Vasotec contained enalapril maleate plus an unidentified stabilizer. (L104.) That implication was ***untrue***. (L104.) Mr. McLeod admitted that the process required "a specified amount of water," but he never specified the amount of water Merck used. (L104.) Too little water would not produce the desired chemical reaction, and too much water would lead to forming a clear solution as in the prior art. McLeod ***concealed*** that the water being added would produce a chemical reaction, and thus ***suppressed*** the aspect of the process that the Apotex patent identifies as a critical improvement over the prior art.

Dr. Scheindlin's declaration as an expert for Apotex in the instant case, (L86-L89, L105-L107), notes that the video conceals the use of sodium bicarbonate. (L106.) The video conceals any chemical reaction between the undisclosed sodium bicarbonate and enalapril maleate. (L106.) The video conceals that one of the products of the chemical reaction is enalapril sodium. (L106.) Dr. Scheindlin specifically stated in his declaration, "Mr. McLeod's use of the word 'stabalizer' in his 1994 testimony ***is deceptive.*** Sodium bicarbonate does not act as a stabalizer per se, but rather is an important ingredient of a chemical reaction to convert enalapril maleate to enalapril sodium." (L106) (emphasis added).

Dr. Schwartz, Merck's own expert in the Canadian action, admitted that he could not tell from those materials whether a reaction occurred. He knew one would get a reaction with

everything in ***solution***, but that is what was already known in the prior art as disclosed in the patents in suit. Dr. Schwartz also admitted that any reaction would depend on the amount of water involved and the order of the mixture, which the video did not explain. He identified several possible roles for sodium bicarbonate in the formula, so the presence of sodium bicarbonate does not reveal the patented process.

Apotex also argued that 35 U.S.C. § 102(g) requires proof that the prior invention was made in the United States, and known to the United States public and that remote disclosure (particularly in view of the fact that Merck concealed that VASOTEC® tablets contained enalapril sodium, disodium maleate, and monosodium maleate and failed to explain that a reaction occurred to convert enalapril maleate to enalapril sodium (L106)) is insufficient to negate a finding of suppression and concealment. Despite the ***unrebutted*** evidence from Apotex's experts that anyone reading the VASOTEC® product monograph could have only one understanding — that each tablet in the bottle, in the physician's hand, and in the patient's mouth contained the active ingredient enalapril maleate, not enalapril sodium, and inactive ingredients including sodium bicarbonate — the district court held that there was no genuine issues of material fact that Merck did not suppress and conceal its invention.

The district court concluded that Apotex failed to raise a genuine issue of material fact as to Merck's affirmative defense, and that no jury could fail to find that Merck had proven invalidity by clear and convincing evidence. The United States Court of Appeals for the Federal Circuit affirmed, further concluding on summary judgment that any suppression and concealment by Merck was unintentional,

even though an internal memo from Merck admitted that if the truth about its process got out it could jeopardize Merck's product approvals world-wide.

In affirming, the Federal Circuit recognized that this case involves "an issue that has not been squarely addressed by this court in considering suppression or concealment as negating prior invention in a defense to an infringement suit under § 102(g) — the burdens of proof governing such a determination." The Federal Circuit, however, interpreted § 102(g) in a manner inconsistent with other sections of the patent laws and inconsistent with the Supreme Court's interpretation of *Kendall v. Winsor*, 62 U.S. (21 How.) 322, 328 (1858); *Anderson v. Liberty Lobby*, 477 U.S. 242 (1986); and *Poller v. Columbia Broadcasting Sys.*, 368 U.S. 464 (1962). The Federal Circuit also denied Apotex's petition for panel rehearing and rehearing en banc. (Pet. App. at 46a-47a.)

REASONS FOR GRANTING THE WRIT

I. This Petition Raises A Question Of Special Importance About Multi-National Drug Companies' Participation In The Patent Systems Of Different Countries.

This case is of special importance and the Court should grant certiorari because it concerns abuse of the patent and court system of the United States and Canada by a multi-national pharmaceutical company. The operation of multi-national drug companies is a topic of major importance for global commerce and health. As can be seen on the front pages of the nation's newspapers, such multi-nationals are

centrally involved in many of the most important policy issues in the world today, from the cost of Merck's drugs for AIDS in Africa[2] to Apotex's manufacture of generic versions of Cipro to battle the threat of Anthrax as a weapon of terror.[3] The specific issue for which Apotex seeks review in ***this*** litigation is that Merck has prevailed on summary judgment on a position diametrically opposed to a position on which it prevailed before in a Canadian litigation, unjustly denying Apotex of its patent on a method of making a drug that Merck for its own benefit suppressed and concealed from the public for years. In this age of global commerce and medicine, one should not be permitted to take opposite positions in the courts of two different countries and prevail in both. For the reasons explained in this petition, Apotex respectfully requests that this Court grant certiorari to review the decision of the United States Court of Appeals for the Federal Circuit and correct the injustice effected in that court's decision.

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2. Barton Gellman, *A Turning Point That Left Millions Behind: Drug Discounts Benefit Few While Protecting Pharmaceutical Companies' Profits*, THE WASHINGTON POST, Dec. 28, 2000, at A1; Karen DeYoung, *Makers of AIDS Drugs Drop S. Africa Suit*, THE WASHINGTON POST, April 19, 2001, at A13; Jon Jeter, *Trial Opens in South Africa AIDS Drug Suit: Firms Seek to Block Law Allowing Generic Substitutes for Patented Medicines*, THE WASHINGTON POST, March 6, 2001, at A1.

3. Amy Harmon & Robert Pear, *Canada Overrides Patent for Cipro to Treat Anthrax*, THE NEW YORK TIMES, October 19, 2001 at A1; Terence Chea, *Drug Firm Plays Defense in Anthrax Scare: For Now, U.S. Declines to Suspend Bayer's Patent and Authorize Generic Cipro*, THE WASHINGTON POST, Oct. 20, 2001 at A4.

II. This Case Presents Important Questions Of Federal Law That Have Not Been, But Should Be, Decided By This Court.

A. Merck must prove that the U.S. public received the benefit of this disclosure.

The origins of the doctrine now codified in § 102(g), favoring a second inventor over a first who has abandoned, suppressed, or concealed the invention, is inherent in the Constitutional basis of the patent laws. *Kendall v. Winsor*, 62 U.S. (21 How.) 322, 328 (1858); *accord*, *Paulik v. Rizkalla*, 760 F.2d 1270, 1273 (Fed. Cir. 1985) (en banc). In *Kendall*, this Court explained that one "who withholds his invention from the public, comes not within the policy or objects of the Constitution or acts of Congress," and therefore refused to invalidate a patent based on concealed prior invention. Permitting Merck to invalidate Apotex's patents in this way frustrates not only the Patent Act, but also the Constitutional basis for the U.S. Patents laws. Accordingly, Merck (who here has the burden of proof) must come forward with clear and convincing evidence to prove that the public ***in the United States*** has gained knowledge of the invention. *See Palmer v. Dudzik*, 481 F.2d 1377, 1387 (C.C.P.A. 1973). Merck has not met that burden. The evidence that the United States public had ***not*** gained knowledge of the invention is set forth above. At the very least there is a genuine issue of material fact on this point, which requires the reversal of summary judgment. The Constitutionally sanctioned purpose "to promote the progress of science and the useful arts" necessarily means to promote the progress of science and the useful arts ***in the United States***. All the Congressional powers listed in art. I, § 8, are of course directed towards the United States. It would entirely frustrate the Constitutional

purpose of the patent laws if one could avoid the consequences of suppression and concealment by revealing the invention only in a foreign location so remote and in such circumstance that there is no reasonable possibility that the United States public ever would receive the benefit of that disclosure.

B. Section 282 required Merck to identify the alleged inventor.

Another reason to grant this writ is to construe a federal statute, 35 U.S.C. § 282 (1994 Supp. V). The district court entered summary judgment of invalidity under 35 U.S.C. § 102(g) (2000), that some unidentified Merck employee had invented the process and that it had not been abandoned suppressed or concealed. But § 282 precludes Merck from even ***asserting*** that defense of prior inventor without first identifying the name and address of the alleged prior inventor.

Section 282 in general concerns practice and procedure in infringement litigation. In § 282, paragraph 1 provides for the presumption of validity and paragraph 2 requires that certain defenses, if asserted, must be pleaded. Paragraph 3, which is relevant here, expressly requires the defendant, Merck to provide certain information in order to even ***assert*** at trial defenses such as invalidity or prior inventorship:

> In actions involving the validity or infringement of a patent the party asserting invalidity or noninfringement shall give notice in the pleadings or otherwise in writing to the adverse party at least thirty days before the trial, of the country, number, date, and name of the patentee of any patent, the title, date, and page numbers of any publication to be relied upon as

> anticipation of the patent in suit or, except in actions in the United States Court of Federal Claims, as showing the state of the art, and ***the name and address of any person who may be relied upon as the prior inventor*** or as having prior knowledge of or as having previously used or offered for sale the invention of the patent in suit. In the absence of such notice proof of the said matters may not be made at the trial except on such terms as the court requires. . . .

35 U.S.C. § 282 (emphasis added). Just as Merck may not assert invalidity without identifying the relevant prior art, so here it may not assert prior inventorship without identifying the alleged prior inventor.

The Federal Circuit considered the presumption of validity under § 282, 1st paragraph, as affecting the relevant burdens of proof under § 102(g). In the context of § 102(g), however, the presumption of validity under § 282, 1st paragraph, is only ***part*** of what the statute requires. That same section also provides ***express*** disclosure requirements that must be met before even ***asserting*** this defense. Because Merck has not provided the statutorily required information, it cannot even assert this defense. This requirement is thus part of Merck's prima facie case as required by statute.

Merck, as the party asserting invalidity under § 102(g), must bear the burden of proving this defense by clear and convincing evidence. Any showing by Merck which does not provide this mandatory, preliminary identification of the name and address of the prior inventor cannot, as a matter of law, suffice as clear and convincing proof of prior inventorship negating suppression and concealment.

The grant of summary judgment must be viewed through the prism of the relevant evidentiary burden, *Anderson v. Liberty Lobby*, 477 U.S. 242, 255-56 (1986), and Merck must at least meet this condition precedent to the defense it seeks to assert.

The importance of identifying the particular alleged prior inventor was underscored by a recent amendment to § 102(g), which added the word "inventor." This amendment did not ***change*** the law, because application of § 102(g) has ***always*** depended on a specific, named inventor, identification of whom has ***always*** been required under § 282. Indeed, the requirement to identify alleged prior inventors by name and address is much, much older than the 1952 Act drafted half a century ago.

The Patent Act of 1793 provided for notice, in writing, thirty days before trial, of any special matter such as "discovery of another person." 1 STAT. 318, § 6 (Feb. 21, 1793). In 1836 Congress retained the requirement of thirty days written notice, adding that the notice must include "names and places of residence." 5 STAT. 117, § 15 (July 4, 1836). The requirement was retained in 1870, 16 STAT. 198, § 61 (July 8, 1870), from which it was codified in Rev. Stat. § 4920. Although the Federal Rules of Civil Procedure superseded that provision, Congress deemed the requirement sufficiently important that it expressly reinstated it in the 1952 act in 35 U.S.C. § 282. *See* 35 U.S.C. § 282, Revision Notes; P.J. Federico, Comments on the New Patent Act, 35 U.S.C.A. (1954), *reprinted in* 75 J.P.T.O.S. 161, 216 (1993). Many cases confirm the requirement of these various acts. *E.g.*, *Roemer v. Simon*, 95 U.S. 214, 219 (1877); *Seymore v. Osborne*, 78 U.S. (11 Wal.) 516, 539, 549 (1870); *Wise v. Allis*, 76 U.S. (9 Wal.) 737, 739–40 (1869); *Agawan Co. v.*

Jordan, 74 U.S. (7 Wal.) 583, 596 (1868); *Teese v. Huntingdon*, 64 U.S. (23 How.) 2, 10 (1859).

Here, it is undisputed that Merck never identified the name and address of the alleged prior inventor, even though it was required to provide that information. Having never provided this information, Merck may not now even assert this defense. Apotex therefore respectfully requests that the previously filed petition for rehearing be granted, that summary judgment in favor of Merck be vacated, and that the case be remanded to the trial court.

III. The Federal Circuit Has Sanctioned So Far A Departure By The District Court From The Accepted And Usual Course Of Judicial Proceedings As To Call For An Exercise Of The Court's Supervisory Powers.

The inconsistent and hypocritical positions Merck has taken in Canada and in the United States amount to a fraud on the patent system. Merck successfully suppressed and concealed this process even as it prosecuted a lawsuit in Canada to enforce its drug patent there. When Apotex discovered that process, despite Merck's suppression and concealment, Merck was then allowed to invalidate Apotex's U.S. patent, destroying its federal property right, on summary judgment. The potential cost of Merck's pharmaceutical fraud could well be billions of dollars. Only the Federal Circuit's radical departure from the usual course of judicial proceedings made possible Merck's fraud. This Court should grant certiorari and intervene to correct that error.

A. The Federal Circuit unacceptably departed from the usual course of judicial proceedings by allowing Merck to obtain summary judgment taking a position opposite to a position on which it has prevailed in an earlier litigation.

The grant of summary judgment directly conflicts with the decision of the Canadian court at *Merck & Co. Inc. v. Apotex Inc.*, [1994] 59 C.P.R. (3d) 133, *reprinted in* L10-L63. Such a conflict with a foreign court is one reason for granting certiorari. *See Aetna Ins. Co. v United Fruit Co.*, 304 U.S. 430, 960 (1938). In *Aetna*, the Court granted certiorari because a decision of a circuit court of appeals was in conflict with the decision of a Court of Queen's Bench on a question of maritime law and insurance. So, here, the decision of the district court and of the Court of Appeals for the Federal Circuit, holding that Merck did not suppress or conceal its alleged prior invention, directly conflicts with the finding of the Canadian court where Merck argued that it did not use the process covered by the patent here in suit.

Judge MacKay in the 1994 Canadian trial found that the experts there could not tell that a reaction converted enalapril maleate to enalapril sodium, the reaction that is crucial to the invention:

> The difficulty encountered is said to be that including the compound enalapril maleate, here said to be the active ingredient, in both VASOTEC and APO-ENALAPRIL, with regularly accepted adjuvants, as the patent indicates, presented a major problem in assuring stability of the product and avoiding undue disintegration. Dr. Sherman, who was directly responsible for overseeing

> product formulation at Apotex, said that in his experience the development of a product for consumption in dosage form where the active ingredient was comparatively small was a "no-brainer", easily accomplished. In this particular case, however, he had encountered the most difficulty of any product development in his experience. From document production by Merck, for counsel's eyes only by agreement, it was apparent that addition of one common adjuvant, sodium carbonate or sodium bicarbonate, was a part of Merck's tablet development and questions were asked in the course of discovery about this. Questions were also raised at trial, of Dr. Schwartz, an expert appearing for the plaintiffs, and Drs. Niebergall and McClelland, experts for the defendant. The questions sought confirmation that the Merck process of tablet formulation may well have been inventive in the manner of its resolution of the problem of disintegration, by producing a reaction through use of sodium carbonate or bicarbonate, and water, that solved the stability problem but left something other than enalapril maleate as the active ingredient. ***None of the experts could confirm this was the inevitable result of the information provided to them***, though all confirmed that ***depending upon the process of mixing and the relative volume of water mixed***, a reaction could be expected.

(L58.) Thus, in the 1994 Canadian trial Merck continued to ***deny*** that a reaction occurred, the very thing that is the claimed novelty of the patented process. Moreover, Merck ***prevailed*** in that position. Merck knew that such a reaction

occurred, and ***did not disclose that fact even to its own expert witness, Dr. Schwartz.*** Merck must now be judicially estopped to assert that it disclosed such a reaction, which is the claimed novelty of the patent in suit.

Indeed, when it suited Merck's purpose it also argued that product labels reflect final contents, not initial ingredients for a chemical reaction. In another Canadian lawsuit in 1999 against Nu-Pharm, Merck relied on the fact that Nu-Pharm's label listed enalapril maleate in its contents as proof that the product contained enalapril maleate and not enalapril sodium. Merck adduced "pictures of bottles of Nu-Enalapril tablets whose ***labels*** indicate that they contain enalapril maleate . . . [and] the ***product monographs*** of Nu-Enalapril and Apo-Enalapril . . . all stating that the Nu-Enalapril tablets contain enalapril maleate." (L72-L73.) Merck's labels and monographs should be interpreted the same way, as falsely indicating that its final product contains enalapril maleate, not enalapril sodium.

This evidence creates a genuine issue as to the underlying fact of Merck's alleged disclosure of its process and whether, instead, Merck intentionally suppressed and concealed its process, thus precluding summary judgment. The Federal Circuit's grant of summary judgment should be reviewed by writ of certiorari.

B. The Federal Circuit unacceptably departed from the usual course of judicial proceedings by ignoring evidence of intentional suppression and concealment creating a genuine issue of material fact.

Patent law distinguishes between two types of suppression or concealment: one in which an inventor ***intentionally*** suppresses or conceals his invention, and another involving a ***legal inference*** of suppression or concealment based on unreasonable delay. *Paulik v. Rizkalla*, 760 F.2d 1270, 1273 (Fed. Cir. 1985). The district court and court of appeals both assumed that this case was about concealment inferred from delay, but Apotex identified evidence of record showing ***intentional*** concealment.

The record on summary judgment is considered in the light most favorable to Apotex, the party opposing the motion. *Poller v. Columbia Broadcasting Sys.*, 368 U.S. 464, 473 (1962). Here, Merck's summary judgment should not have been granted. Summary procedures should be used sparingly in complex litigation where motive and intent play leading roles, the proof is largely in the hands of the alleged tortfeasors, and hostile witnesses thicken the plot. *Id.* In *Poller* this Court considered an antitrust case, but patent litigation is no less complex. Proof of Merck's intentional concealment, like proof of the conspiracy in *Poller*, is largely in the hands of the party that here received summary judgment. As the Court in *Poller* noted:

> It is only when the witnesses are present and subject to cross-examination that their credibility and the weight to be given their testimony can be appraised. Trial by affidavit is no substitute for

> trial by jury which so long has been the hallmark of "even handed justice."

Poller, 368 U.S. at 473 (1962).

The record indicates that Merck misled the public to protect its financial interest in VASOTEC. To designedly withhold an invention from the public for one's own benefit is to suppress it. *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1567 (Fed. Cir. 1996).

In an internal document, Merck admitted:

> [W]e have a major concern regarding the presence of a statement on the product label which infers the formation of a sodium salt of enalapril maleate. ***Such a statement might affect worldwide registration of the product and existing approved labeling.***

(L108) (emphasis added). This statement reveals Merck's motive to suppress and conceal the reaction that forms "a sodium salt of enalapril maleate", i.e., enalapril sodium. ***That very reaction is crucial to the invention.*** Given this evidence of motive, the inference of intent reasonably could (and on summary judgment was required to be) drawn in Apotex's favor.

Some commentators on patent law suggest that such ***intentional*** suppression and concealment in patent law ***cannot*** be cured. *See* Robert L. Harmon, PATENTS AND THE FEDERAL CIRCUIT 108–109 (4th ed. 1998) ("[D]eliberate suppression or concealment of an invention . . . ***is probably not curable by resumption of work***. . . .") (emphasis added).

Even if Merck can negate its deliberate suppression and concealment, it must prove clearly and convincingly that the public has gained knowledge of the invention to insure its preservation in the public domain. *Palmer*, 481 F.2d at 1387 ("[T]he question . . . ought to be determined by asking whether the public has gained ***knowledge of the invention*** which will ***insure its preservation*** in the public domain.") (emphasis added). One who keeps knowledge of the invention from the public suppresses that invention. *Young v. Dworkin*, 489 F.2d 1277, 1279 (C.C.P.A. 1974).

Apotex offered evidence that a mock-up video Merck used in the 1994 Canadian trial suppressed the patented process by concealing a chemical reaction that converted enalapril maleate to enalapril sodium without forming a clear solution in water. McLeod, who narrated the video, admitted it was "not really enalapril or the ingredients." He admitted that Merck "chose not to use the active ingredients," even though "there was no reason not to."

Dr. Sherman's declaration notes that McLeod admitted that the process required "a specified amount of water," but that he never specified the amount Merck used. (L104.) Dr. Schwartz, Merck's expert in the 1994 Canadian suit, admitted that he could not tell whether the required reaction occurred. He knew one would get a reaction with everything in ***solution*** but that is shown in the prior art as disclosed in the patents in suit. Dr. Schwartz also admitted that any reaction would depend on the ***amount*** of water involved and the ***order*** of the mixture, which the video concealed. He identified several possible roles for sodium bicarbonate, thus confirming that the presence of sodium bicarbonate does not reveal the patented process. Similarly, Apotex's experts in Canada, Drs. Niebergall and McClelland, could not be sure

that a reaction occurred because no information was given about whether there was enough water. (L58.)

Dr. Scheindlin and Dr. Sherman both attest that the video conceals: (1) the use of sodium bicarbonate; (2) any chemical reaction between the sodium bicarbonate and enalapril maleate; and (3) that a chemical reaction produces, inter alia, enalapril sodium. (L104-L106.) Merck has conceded that McLeod admitted he never identified sodium bicarbonate, but merely mentioned the presence of an unnamed stabilizer. Dr. Scheindlin specifically stated, "Mr. McLeod's use of the word 'stabilizer' in his 1994 testimony ***is deceptive.*** Sodium bicarbonate does not act as a stabilizer per se, but rather is an important ingredient of a chemical reaction to convert enalapril maleate to enalapril sodium." (L106) (emphasis added). Dr. Sherman confirmed that the implication that VASOTEC contained enalapril maleate plus an unidentified ***stabilizer***, was ***untrue***. (L104.)

The testimony of Merck's expert Dr. Schwartz in the 1994 Canadian trial, that no reaction could be shown to have occurred, is analogous to the testimony of the prior inventor's technical director in *Palmer*, 481 F.2d at 1384–85. Just like the testimony in *Palmer*, the prior testimony of Dr. Schwartz "indicates that the invention was not necessarily apparent even to one skilled in the art." *Id.* In *Palmer*, the C.C.P.A. noted that this fact "supports the legal conclusion of the board that Palmer concealed the invention within the meaning of § 102(g)." So, here, the ***fact*** that Dr. Schwartz did not appreciate that a reaction occurred is ***material*** to the legal conclusion of suppression and concealment.

C. The record as a whole does not clearly and convincingly show the absence of a genuine issue of fact.

In its new drug application ("NDA") on VASOTEC, its product labeling, the 1988 *Dictionnairre Vidal*, and the Product Monograph, Merck stated that the contents of the ***final tablet*** that would be sold would include enalapril maleate and sodium bicarbonate, when in truth the final contents are enalapril sodium and byproducts of a enalapril maleate/sodium bicarbonate reaction. By listing starting ingredients ***as though they were final contents***, Merck intentionally suppressed and concealed the reaction crucial to the patented process. Merck conceded that VASOTEC tablets contain enalapril sodium and ***not*** enalapril maleate, and that it ***never*** publicly disclosed, (in the *Dictionnairre Vidal*, the Product Monograph, or elsewhere), that VASOTEC tablets contain enalapril sodium or that the enalapril maleate is reacted in the tableting process.

There is no *evidence* in the record that anyone would interpret Merck's descriptions as the starting ingredients for a manufacturing process. All the ***evidence*** supports Apotex. Dr. Scheindlin (L86-L89, L105-L107), Dr. Carstensen (L82-L85), and Dr. Sherman (L90-L104), explained that anyone reading the product monograph could have only one understanding — that each tablet in the bottle, in the physician's hand, and in the patient's mouth contained the active ingredient enalapril maleate, not enalapril sodium, and inactive ingredients including sodium bicarbonate.

Dr. Scheindlin also identified false and misleading statements in Merck's NDA that suppressed and concealed

the process. Merck was supposed to disclose the contents of the final VASOTEC tablets in subsection 7 of its 1983 NDA for VASOTEC tablets. Instead it repeated the initial ingredients from subsection 6. Merck conceded that it there concealed that VASOTEC tablets contained enalapril sodium, disodium maleate, and monosodium maleate. In subsection 8, where Merck was supposed to identify the details in its manufacturing process, it never explained that a reaction occurred to convert enalapril maleate to enalapril sodium.

Apotex's inability to reverse engineer the process in 1990 (before Dr. Sherman's invention) is additional evidence of Merck's effective suppression and concealment. Apotex used the description of contents in the physician's desk reference plus its analysis that suggested the presence of sodium bicarbonate. Apotex found that stability actually ***decreased*** when it mixed these two components without using the patented process. Thus, listing of enalapril maleate (and ***not*** enalapril sodium) as the contents of VASOTEC effectively concealed and suppressed the process even when Apotex tried to reverse engineer it.

Whenever § 102(g) is an issue in litigation, there is always at least one person who uncovered the invention despite any concealment and suppression — the subsequent inventor. Because of the statutory presumption of validity, and in the absence of derivation, that person's inventive insight cannot itself be clear and convincing evidence on summary judgment to negate suppression and concealment. Here, the only proof offered of the ***sufficiency*** of Merck's disclosures to negate suppression and concealment is that Dr. Sherman admitted: (1) that the final enalapril sodium product in the VASOTEC® tablets was the result of an acid-base chemical reaction between enalapril maleate and sodium

bicarbonate in water; and (2) that his inspection of the VASOTEC® tablets that Merck sold commercially revealed that they were made using a wet granulation process. (Pet. App. at 16a-17a.) This evidence is insufficient.

Dr. Sherman's supposed admissions were, in fact, the insights of another inventor who had been studying the problem since 1990. Indeed, his "Statement of Facts" containing the alleged admissions was made in the three-week interval between his conception and reduction to practice. At this juncture it must be presumed (drawing all inferences in Apotex's favor) that Dr. Sherman ***did not*** derive his invention, because the district court found in another motion not appealed that this issue was genuinely disputed. Moreover, the Patent Office concluded that the process Dr. Sherman invented and claimed was patentable over the prior art, including Merck's patent on enalapril maleate and other patents on other processes for making it. Dr. Sherman's invention is therefore not evidence negating suppression and concealment, because the non-derived invention of another inventor in Canada is not probative of whether the United States ***public*** has gained knowledge of the invention that will insure its preservation in the public domain.

On the contrary, all the evidence about what the ***United States public*** might have known shows that Merck's intentional suppression was effective. The 1994 Canadian trial included the product monograph and the testimony of McLeod that Merck relies on as its disclosures. Expert witnesses there, however, could not say whether Merck used the now patented process. Even Merck's own expert witness Dr. Schwartz, the only member of the United States public there present, did not know. If Dr. Schwartz (who knows more about this field than the general United States public)

did not know of this reaction, that is substantial evidence that the process was still effectively suppressed and concealed. MacKay, J., in the passage quoted above, described the suggested process as "inventive" and concluded that he could not find, on evidence including the monograph and McLeod's testimony, that any such reaction occurred. MacKay, J., in effect, concluded the opposite of the supposed admissions in the Statement of Facts.

The grant of summary judgment premised on a contrary finding should be reviewed by writ of certiorari. Even if Dr. Sherman's supposed admissions were probative, which they are not, they still would not be dispositive. Even if it was known to use a wet granulation process, such a process may be performed using not only water but also alcohol — the product monograph indicated that enalapril maleate is more soluble in the latter. And even if it were known to use water to permit a reaction, one still would not know from looking at the tablet to use the patented process instead of the known prior art process, which produced that result. Although it is possible to analyze VASOTEC tablets to determine that they contain sodium, it is not possible to reverse engineer the process by which they are made and, in particular, it is not possible to discern by reverse engineering that they do not use the known prior art process.

CONCLUSION

For the reasons set forth above, Apotex respectfully requests that certiorari to the United States Court of Appeals for the Federal Circuit be granted for the purpose of reviewing its grant of summary judgment in this litigation.

Respectfully submitted,

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APPENDIX A — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT DATED AND DECIDED JUNE 8, 2001

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

00-1272

APOTEX USA, INC.,

Plaintiff-Appellant,

v.

MERCK & CO., INC.,

Defendant-Appellee.

DECIDED: June 8, 2001

Before LOURIE, CLEVENGER, and LINN, *Circuit Judges*.

LOURIE, *Circuit Judge*.

Apotex USA, Inc. appeals from the decision of the United States District Court for the Northern District of Illinois granting Merck & Co., Inc.'s motion for summary judgment that the claims of U.S. Patents 5,573,780 and 5,690,962 are invalid under 35 U.S.C. § 102(g). *Apotex Corp. v. Merck & Co.*, No. 96-C-7375, 2000 WL 97,582 (N.D. Ill. Jan. 25, 2000) ("*Apotex I*"). Because the district court did not err in granting summary judgment that the '780 and '962 patents are invalid under 35 U.S.C. § 102(g), we affirm.

Appendix A

BACKGROUND

Apotex is the assignee of the '780 and '962 patents, which relate to a process for making a stable solid formulation of enalapril sodium for use in the treatment of high blood pressure. *Apotex I* [2000 WL 97582,] at *1. Claim 1 of the '780 patent, which is representative of the claims at issue, reads as follows:

> 1. A process of manufacture of a pharmaceutical solid composition comprising enalapril sodium, which process comprises the steps of:
>
> i) a) mixing enalapril maleate with an alkaline sodium compound and at least one other excipient, adding water sufficient to moisten, and mixing to achieve a wet mass, or
>
> b) mixing enalapril maleate with at least one excipient other than an alkaline sodium compound, adding a solution of an alkaline sodium compound in water, sufficient to moisten and mixing to achieve a wet mass; thereby to achieve a reaction without converting the enalapril maleate to a clear solution of enalapril sodium and maleic acid sodium salt in water,
>
> ii) drying the wet mass, and
>
> iii) further processing the dried material into tablets.

'780 patent, col. 5, l. 34 to col. 6, l. 15. The claims of the '962 patent, which is a continuation of the application that led to the '780 patent, are identical to those found in the '780 patent except that they are not restricted to tablet form, but rather encompass any solid pharmaceutical dosage form of enalapril sodium. '962 patent, col. 5, l. 22 to col. 6, l. 11. This distinction is not material to the resolution of this appeal.

Merck manufactures enalapril sodium under the trade name VASOTEC®, and has been continuously manufacturing and commercially selling VASOTEC® tablets since 1983. *Apotex I* at *7. Merck owns both U.S. and Canadian patents covering the enalapril sodium compound, but does not own a patent covering its process of manufacturing VASOTEC®. *Id.* at *1. However, in 1992, Merck disclosed the ingredients utilized in its VASOTEC® manufacturing process in a Canadian product monograph, and more than 30,000 copies of the monograph were distributed in 1993 alone. *Id.* at *7. Merck also disclosed the ingredients used in manufacturing RENITEC® (the trademark used for its enalapril sodium product sold in various foreign countries) in the 1988 edition of the Dictionnaire Vidal, a French pharmaceutical dictionary. *Id.*

In 1991, Merck and its Canadian subsidiary, Merck Frosst Canada, Inc., sued Apotex's Canadian affiliate, Apotex Canada, for infringement of Merck's Canadian patent covering the enalapril sodium compound. *Id.* at *1. During the 1994 trial ("the Canadian trial"), Brian McLeod, Merck's then-vice president of marketing, performed a step-by-step narration of a videotape demonstrating Merck's process of manufacturing VASOTEC®. *Id.* Within days of hearing this

testimony, Dr. Bernard Sherman, an Apotex official, allegedly conceived the patented process at issue. *Id.*

Apotex filed the present action against Merck, alleging that Merck's process of manufacturing VASOTEC® infringes all of the claims of both the '780 and '962 patents. *Id.* Both parties filed cross-motions for summary judgment on the issue of infringement, and Merck cross-moved for summary judgment of invalidity under § 102(g). *Id.* The district court granted Apotex's motion for summary judgment of infringement, but also granted Merck's cross-motion for summary judgment of invalidity because it found that Merck invented the process claimed in the '780 and '962 patents within the United States before Apotex, and did not abandon, suppress, or conceal that invention within the meaning of § 102(g). *Id.* at *9.

Apotex thereafter filed a motion asking the court to reconsider its grant of summary judgment of invalidity, which the district court denied. *Apotex Corp. v. Merck & Co.*, No. 96-C-7375, 2000 WL 656,670 (N.D. Ill. Mar. 17, 2000). Apotex appeals from the district court's grant of summary judgment of invalidity. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1) (1994).

DISCUSSION

Summary judgment is appropriate "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." FED. R.

CIV. P. 56(c). For purposes of the motion, "[t]he evidence of the nonmovant is to be believed, and all justifiable inferences are to be drawn in his favor." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). We review a district court's grant of a motion for summary judgment *de novo*. *Ethicon Endo-Surgery, Inc. v. United States Surgical Corp.*, 149 F.3d 1309, 1315, 47 USPQ2d 1272, 1275 (Fed. Cir. 1998).

Apotex argues that the district court improperly invalidated the '780 and '962 patents because Merck failed to prove by clear and convincing evidence that it did not suppress or conceal the patented process. Apotex contends that proof of invalidity under § 102(g) requires Merck to prove that it did not suppress or conceal the process of manufacturing VASOTEC® tablets based on its activities within the United States, and that Merck's foreign disclosures therefore cannot be used to satisfy its burden of proof. Apotex also contends that, in any event, Merck's foreign disclosures fail to prove that it did not suppress or conceal the process because nothing in the testimony from the Canadian trial, the product monograph, or the French dictionary disclosed the use of water, the occurrence of an acid-base chemical reaction between enalapril maleate and sodium bicarbonate, or the resultant enalapril sodium product. Finally, Apotex argues that the evidence demonstrates that Merck in fact suppressed or concealed its invention by failing to file a patent application on the process, by submitting misleading information in its New Drug Application ("NDA") that only disclosed the starting ingredients used to make VASOTEC®, and by preventing the details of its process from circulating outside of the company.

Merck responds that § 102(g) only requires proof that the prior invention was made in the United States, and that evidence of lack of suppression or concealment can be proven by both foreign and domestic activities. Merck further argues that it did not suppress or conceal the process because it used it commercially, disclosed it in open court directly to its competitor, and published the ingredients used to make VASOTEC® tablets in both the product monograph and the French dictionary. Merck also argues that the submissions it made with respect to its NDA were proper and in any event could not constitute suppression or concealment because it was the Food and Drug Administration that never made those submissions public. Finally, Merck contends that the process was not suppressed or concealed because it was obvious and Dr. Sherman admitted that VASOTEC® tablets could be reverse-engineered to reveal the details of the process.

Section 102(g) operates to ensure that a patent is awarded only to the "first" inventor in law. In addition to governing priority determinations in interference proceedings in the United States Patent and Trademark Office, § 102(g) may be asserted as a basis for invalidating a patent in defense to an infringement suit. *New Idea Farm Equip. Corp. v. Sperry Corp.*, 916 F.2d 1561, 1566, 16 USPQ2d 1424, 1428 (Fed. Cir. 1990) (citation omitted). That section provides in relevant part that: "A person shall be entitled to a patent unless . . . before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it." 35 U.S.C.A. § 102(g) (West Supp. 2000). Therefore, if a patentee's invention has been made by another, prior inventor who has not abandoned, suppressed, or concealed the invention,

§ 102(g) will invalidate that patent. *New Idea*, 916 F.2d at 1566, 16 USPQ2d at 1428.

Apotex does not dispute that Merck invented the patented process in the United States well before Dr. Sherman's alleged date of conception. Apotex also concedes that Merck did not abandon its process of manufacturing VASOTEC® tablets as shown by its continuous commercial use of the process since 1983. The sole issue on appeal, therefore, is whether Merck "suppressed" or "concealed" the process within the meaning of § 102(g). Whether suppression or concealment has occurred is a question of law, which we review *de novo*. *Brokaw v. Vogel*, 429 F.2d 476, 480, 166 USPQ 428, 431 (CCPA 1970).

As an initial matter, we disagree with Apotex's interpretation of § 102(g) as requiring proof negating suppression or concealment to arise from activities occurring within the United States. The plain language of § 102(g) clearly requires that the prior invention be made "in this country." However, in light of the grammatical structure of § 102(g), it would be a strained reading of that provision to interpret the language "in this country" to also modify the requirement that the prior invention was "not . . . abandoned, suppressed, or concealed." A more reasonable interpretation is that it only modifies the antecedent verb "made," but not the "abandoned, suppressed, or concealed" clause that follows it. Had Congress intended the phrase "in this country" to modify "abandoned, suppressed, or concealed," it would have inserted language to that effect.

Indeed, if there were any doubt, the legislative history of § 102(g) demonstrates that Congress contemplated that

precise modification, as it applied to another clause in § 102(g), and failed to adopt it. An earlier version of that provision considered in the House read as follows:

> [B]efore the applicant's invention thereof the invention was in fact made **in this country** by another who had not abandoned it and who was using reasonable diligence **in this country** in reducing it to practice or had reduced it to practice.

H.R. 3760, 82nd Cong. (1951) (emphasis added). The fact that the drafters found it desirable to emphasize that the language "in this country" applies to "using reasonable diligence" as well as to the word "made" supports the conclusion that it only modifies the verb that precedes it and not any subordinate clause that follows it. Accordingly, based upon the plain language of § 102(g) and the relevant legislative history of that provision, we conclude that the language "in this country" only applies to the country where "the invention was made," and that proof negating suppression or concealment is not limited to activities occurring within the United States.

We next turn to an issue that has not been squarely addressed by this court in considering suppression or concealment as negating prior invention in a defense to an infringement suit under § 102(g) — the burdens of proof governing such a determination. Section 282 of the Patent Act provides that "[a] patent shall be presumed valid." 35 U.S.C.A. § 282 (West Supp. 2000). In order to overcome the presumption of validity, the party challenging a patent must prove facts supporting a determination of invalidity by clear

and convincing evidence. *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1360, 220 USPQ 763, 770 (Fed. Cir. 1984). Section 282 applies with full force to a § 102(g) defense, and thus a party asserting invalidity under § 102(g) must prove facts by clear and convincing evidence establishing a prior invention that was not abandoned, suppressed, or concealed. *See Kimberly-Clark Corp. v. Procter & Gamble Distrib. Co.*, 973 F.2d 911, 915, 23 USPQ2d 1921, 1924 (Fed. Cir. 1992).

In *Young v. Dworkin*, one of our predecessor courts set forth the relevant burdens of proof governing a determination whether a prior invention was suppressed or concealed, in the context of an interference between co-pending applications, as follows:

> The sole remaining question is whether the board correctly held that junior party-appellant suppressed or concealed his invention within the meaning of 35 U.S.C. § 102(g). Here, the senior party-appellee bears the burden of proof by a preponderance of the evidence, notwithstanding junior party-appellant's burden on the issue of priority of invention which he has sustained.

Young v. Dworkin, 489 F.2d 1277, 1279, 180 USPQ 388, 390 (CCPA 1974) (citing *Gallagher v. Smith*, 206 F.2d 939, 99 USPQ 132 (CCPA 1953)). Thus, under § 102(g) interference law involving co-pending applications, once the first party to invent has established priority of invention, the second party to conceive and reduce the invention to practice has the burden of proving that the first party suppressed or

concealed the invention. In such an interference, the first party to invent does not bear any burden of proof regarding suppression or concealment once it has established an earlier date of invention.

A § 102(g) prior invention defense is governed by the identical "suppressed or concealed" language applicable to priority determinations in interference proceedings. 35 U.S.C. § 102(g). We must therefore interpret the § 102(g) defense provision consistently with established interference law. However, infringement actions implicating a § 102(g) defense differ from interferences in that a patent has been granted on the invention at issue, and therefore the presumption of validity under § 282 applies.[1] Because the patentee (analogous to the second-to-invent in the interference context) has the benefit of the presumption of validity, that party should only be held to bear a burden of

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1. Generally speaking, the presumption of validity does not apply to patents involved in interference proceedings, and thus the invalidity of a patent involved in an interference under § 102(g) need only be proven by preponderant evidence. *See Bruning v. Hirose*, 161 F.3d 681, 686, 48 USPQ2d 1934, 1938 (Fed. Cir. 1998) (holding that, in an interference involving a patent issued from an application that was co-pending with the interfering application, the appropriate standard of proof for validity challenges is the preponderance of the evidence standard because the presumption of validity is inapplicable). However, the presumption may effectively be implicated in the case of a priority contest between an issued patent and an application that was filed after the issuance of the patent. In such a situation, the junior party must establish priority of invention by clear and convincing evidence. *Price v. Symsek*, 988 F.2d 1187, 1194, 26 USPQ2d 1031, 1036 (Fed. Cir. 1993). Such a factual scenario is not before us.

producing evidence indicating that the prior inventor may have suppressed or concealed the invention once the challenger (analogous to the first-to-invent in the interference context) has established prior invention by clear and convincing evidence. That burden bears a rough similarity to placing the burden of proving suppression or concealment on the second-to-invent under interference law, but at the same time is appropriately limited to one of production, not persuasion, giving due regard to the presumption of validity.

We therefore interpret § 102(g) as requiring that once a challenger of a patent has proven by clear and convincing evidence that "the invention was made in this country by another inventor," 35 U.S.C. § 102(g), the burden of production shifts to the patentee to produce evidence sufficient to create a genuine issue of material fact as to whether the prior inventor has suppressed or concealed the invention. However, in accordance with the statutory presumption in 35 U.S.C. § 282, the ultimate burden of persuasion remains with the party challenging the validity of the patent. *See Innovative Scuba Concepts, Inc. v. Feder Indus., Inc.*, 26 F.3d 1112, 1115, 31 USPQ2d 1132, 1134 (Fed. Cir. 1994) ("While a patentee may have the burden of going forward with rebuttal evidence once a challenger presented a *prima facie* case of invalidity, the presumption of validity remains intact and the ultimate burden of proving invalidity remains with the challenger throughout the litigation." (citing *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1376, 231 USPQ 81, 87 (Fed. Cir. 1986))). Once the patentee has satisfied its burden of production, the party alleging invalidity under § 102(g) must rebut any alleged suppression or concealment with clear and convincing evidence to the contrary.

Appendix A

Our case law distinguishes between two types of suppression or concealment. The first is implicated in a situation in which an inventor actively suppresses or conceals his invention from the public. *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1567, 39 USPQ2d 1895, 1901 (Fed. Cir. 1996) (citing *Kendall v. Winsor*, 62 U.S. (21 How.) 322, 328 (1858)). The second involves a legal inference of suppression or concealment based upon an unreasonable delay in filing a patent application.[2] *Peeler v. Miller*, 535 F.2d 647, 655, 190 USPQ 117, 122 (1976) (holding that a four-year delay in filing a patent application after the invention was perfected was unreasonably long); *Shindelar v. Holdeman*, 628 F.2d 1337, 1342, 207 USPQ 112, 116 (1980) (finding suppression or concealment because no reasonable explanation was given for the two-year and five-month delay between reduction to practice and the filing of a patent application). The latter type is involved here.

Although a prior inventor implicated in a § 102(g) infringement defense may not have filed a patent application, in contrast to an interference contestant, that party's delay in otherwise bringing the knowledge of the invention to the public may nevertheless raise a similar inference of suppression or concealment. *See Int'l Glass Co. v. United States*, 408 F.2d 395, 403, 159 USPQ 434, 441 (Ct. Cl. 1969)

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2. A subset of the category of "inferred" suppression or concealment arises in a situation in which the first inventor is "spurred" into filing a patent application by another application, *Mason v. Hepburn*, 13 App.D.C. 86 (D.C. Cir. 1898), or by the commercial activity of another, *Woofter v. Carlson*, 367 F.2d 436, 445-446, 151 USPQ 407, 416 (CCPA 1967). This case does not involve "spurring."

(holding that the prior invention of a process did not invalidate a patent on the same process under § 102(g) because the prior inventor did nothing to make the invention known to the public). Even though there is no explicit disclosure requirement in § 102(g), the spirit and policy of the patent laws encourage an inventor to take steps to ensure that "the public has gained knowledge of the invention which will insure its preservation in the public domain" or else run the risk of being dominated by the patent of another. *Palmer v. Dudzik*, 481 F.2d 1377, 1387, 178 USPQ 608, 616 (CCPA 1973); *see also Kimberly-Clark Corp. v. Johnson & Johnson*, 745 F.2d 1437, 1446, 1453, 223 USPQ 603, 607, 614 (Fed. Cir. 1984) (defining § 102 "prior art" to be "technology already available to the public," and stating that "secret prior art" may not be used to invalidate a patent under § 102(g)); *Oddzon Prods., Inc. v. Just Toys, Inc.*, 122 F.3d 1396, 1402, 43 USPQ2d 1641, 1645 (Fed. Cir. 1997) ("[W]hen the possessor of secret prior art (art that has been abandoned, suppressed, or concealed) that predates the critical date is faced with a later-filed patent, the later-filed patent should not be invalidated in the face of this 'prior' art, which has not been made available to the public. Thus, prior, but non-public, inventors yield to later inventors who utilize the patent system."). Absent a satisfactory explanation for the delay or the presence of other mitigating facts, a prior invention will therefore be deemed suppressed or concealed within the meaning of § 102(g) "if, within a reasonable time after completion, no steps are taken to make the invention publicly known." *Int'l Glass*, 408 F.2d at 403, 161 USPQ at 441.

In the case at hand, we find that Apotex has satisfied its burden of producing evidence sufficient to create a genuine

issue of material fact that Merck suppressed or concealed its process of manufacturing enalapril sodium tablets. We emphasize at the outset that although § 102(g) prior art must be somehow made available to the public in order to defeat another patent, a § 102(g) prior inventor is under no obligation to file a patent application. *Checkpoint Sys., Inc. v. United States Int'l Trade Comm'n*, 54 F.3d 756, 763, 35 USPQ2d 1042, 1048 (Fed. Cir. 1995). Thus, while Merck's failure to file a patent application may be relevant to a determination whether it suppressed or concealed its process, especially if there were evidence that such failure was based on a decision to retain the invention as a trade secret, that failure alone does not satisfy the patentee's burden of producing evidence sufficient to create a genuine issue of material fact of suppression or concealment. *See E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 1437, 7 USPQ2d 1129, 1135 (Fed. Cir. 1988) (explaining that a patent application need not be filed on an invention for it to be considered § 102(g) prior art as long as the invention is found not to have been abandoned, suppressed, or concealed).

However, Apotex did allege that Merck failed to make its invention publicly known. Merck perfected its process and began commercially using the process to manufacture VASOTEC® tablets no later than 1983. Although Merck argues that its process was disclosed to the public because its VASOTEC® tablets could have been reverse-engineered, that argument is based on the admissions of Dr. Sherman, who drew upon the information provided in Merck's subsequent disclosures to determine the details of the

process.[3] Thus, it appears that Merck took no steps to make the invention publicly known for nearly five years, when it first published the ingredients used in its process in the 1988 edition of the Dictionnaire Vidal. We find that such a delay raises an inference that Merck suppressed or concealed its invention. Accordingly, because Apotex has successfully discharged its burden of going forward with evidence creating a genuine issue of material fact of suppression or concealment, the burden shifts to Merck to rebut that showing by clear and convincing evidence to the contrary.

We conclude that Merck has succeeded in rebutting the inference of suppression or concealment created by its period of inactivity by clear and convincing evidence. In *Paulik v. Rizkalla*, we stated the rule that "the first inventor will not be barred from relying on later, resumed activity antedating an opponent's entry into the field, merely because the work done before the delay was sufficient to amount to a reduction to practice." 760 F.2d 1270, 1275, 226 USPQ 224, 228 (Fed. Cir. 1985) (holding that the inference of suppression or concealment from a four-year delay between reduction to practice and the filing of a patent application was overcome by the first inventor's resumption of activity before the

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3. It is worth noting that if it were clear that Merck's process could be reverse-engineered by one of ordinary skill through an inspection of VASOTEC® tablets, Apotex could not benefit from the inference of suppression or concealment because Merck could not be said to have delayed in making the benefits of its invention known to the public. *See Palmer*, 481 F.2d at 1386-87 (stating that a commercial use of an invention will preclude a finding of suppression or concealment only when such use enables the public to learn of the invention).

second inventor's date of conception). Thus, even though Merck may have suppressed or concealed the process for a period of time after it reduced it to practice in 1983, as long as it "resumed activity" (*i.e.*, made the benefits of its invention known to the public) before Apotex's entry into the field, it cannot be deemed to have suppressed or concealed the invention within the meaning of § 102(g).

Merck made several disclosures following its period of suppression or concealment that made the invention publicly known, all of which took place before Apotex's entry into the field (here, Dr. Sherman's alleged conception in April of 1994). First, Merck disclosed the ingredients used in manufacturing VASOTEC® tablets in the 1988 edition of the Dictionnaire Vidal. It also widely distributed the product monograph in Canada from October 1992 through 1994, which similarly disclosed the ingredients it used in its manufacturing process. Merck also provided a step-by-step description of the process through the testimony given by Brian McLeod at the Canadian trial on March 28, 1994.

Apotex argues that these disclosures inadequately described Merck's process of manufacturing VASOTEC® tablets, and therefore that the public never received the benefit of the invention. However, Dr. Sherman admitted both in his deposition in this case and in his 1994 Statement of Facts prepared for the Canadian trial that his inspection of the VASOTEC® tablets that Merck sold commercially revealed that they were made using a wet granulation process. He also admitted that, after learning of the disclosed starting ingredients from the Canadian product monograph (which included sodium bicarbonate), it "immediately occurred" to

him and was "obvious to any knowledgeable formulator or chemist" that the final enalapril sodium product in the VASOTEC® tablets was the result of an acid-base chemical reaction between enalapril maleate and sodium bicarbonate in water. Merck's various disclosures, in conjunction with Apotex's admissions, therefore clearly and convincingly prove that Merck made the knowledge of its invention available to the public, thereby satisfying its burden of rebutting Apotex's evidence of suppression or concealment.

Moreover, Apotex's argument that Merck suppressed or concealed the process by submitting misleading information to the FDA in 1983 is irrelevant because any suppression that was implicated was overcome by Merck's subsequent activity. We therefore conclude that the district court did not err in granting summary judgment that the '780 and '962 patents are invalid under § 102(g).

We have considered Apotex's remaining arguments and find them to be unpersuasive.

CONCLUSION

Because the district court did not err in granting summary judgment that the '780 and '962 patents are invalid under 35 U.S.C. § 102(g), we

AFFIRM.

APPENDIX B — MEMORANDUM OPINION AND ORDER OF THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS, EASTERN DIVISION DATED AND DECIDED JANUARY 20, 2000 AND DOCKETED JANUARY 25, 2000

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS,
EASTERN DIVISION

Case No. 96 C 7375

APOTEX CORP.,

Plaintiff,

v.

MERCK & CO., INC.,

Defendant.

January 20, 2000, Decided
January 25, 2000, Docketed

MEMORANDUM OPINION AND ORDER

MATTHEW F. KENNELLY, District Judge:

In this patent infringement suit, Apotex Corporation accuses Merck & Co. of infringing two patents held by Apotex, U.S. Patent No. 5,573,780 and U.S. Patent No. 5,690,962. The parties filed cross motions for summary judgment on the infringement issue, and in addition, Merck

has filed a motion for summary judgment that the patents are invalid. We address each motion below.

FACTUAL BACKGROUND

The Patent and Trademark Office issued Patent No. 5,573,780 (the '780 Patent), entitled "Stable Solid Formulation of Enalapril Salt and Process for Preparation," to Dr. Bernard Sherman on November 12, 1996. The PTO issued Patent No. 5,690,962 (the '962 Patent), which is a continuation of the '780 Patent and therefore shares the same title, on November 25, 1997. Sherman assigned his rights in both patents to Apotex. The patents cover a process for making a pharmaceutical compound for use in the treatment of high blood pressure. In the simplest of terms, the patented process involves mixing the active ingredient, enalapril maleate, with an alkaline sodium compound and at least one other inactive ingredient or "excipient,"[1] adding water to the mix, drying the mix and processing the dried mix into tablets. The claimed novelty of the invention was that it produced a stable compound "without requiring the steps of suspending the enalapril maleate in water, adding the alkaline sodium compound and mixing until the reaction is complete and a clear solution is formed." U.S. Patent No. 5,573,780, col. 1, line 65 – col. 2, line 4; U.S. Patent No. 5,690,962, col. 1, line 65 – col. 2, line 4. In this lawsuit, Apotex accuses Merck of infringing all of the claims of its two patents.

Before we turn to the merits of the parties' summary judgment motions, a bit of history is in order. This is not the

1. An excipient is an inert substance added to a mixture to give it bulk or some other desirable characteristic.

first time these parties have sparred over their respective rights to patents involving the drug enalapril maleate. In 1991, Merck and its Canadian subsidiary, Merck Frosst Canada, Inc., sued Apotex's Canadian affiliate, Apotex Canada, for infringement of Merck Frosst's patent that claims the drug substance enalapril. The record does not permit the Court to determine whether the Canadian patent Merck sought to enforce in the Canadian litigation covers the same process Apotex attacks in this lawsuit. Nor is it clear what process or product of Apotex's Merck was accusing of infringement in that litigation, though it clearly was not the process covered in the '780 and '962 Patents because Sherman had not yet conceived of that process. But Merck's process for making VASOTEC — the accused process here — was definitely at issue in the Canadian litigation because as part of its case, Merck played a videotape of one of its employees demonstrating the process, and Merck's then vice president of marketing, Brian McLeod, took the stand to narrate the tape and to give a play-by-play of the process.

The outcome of the Canadian litigation is not important for our purposes. However, the trial is relevant here because it set the stage for this lawsuit: Sherman apparently conceived of the patented process within days after McLeod testified about Merck's process.

DISCUSSION

1. Applicable Legal Standard

The Federal Circuit has stated that summary judgment is as appropriate in a patent case as it is in any other case.

See, e.g., *Avia Group International, Inc. v. L.A. Gear California, Inc.*, 853 F.2d 1557, 1561 (Fed. Cir. 1988). Thus, summary judgment is appropriate when there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law. FED. R. CIV. P. 56(c). In determining whether there is a genuine issue of fact, we view the evidence and draw all reasonable inferences in favor of the party opposing the motion. See *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23, 91 L. Ed. 2d 265, 106 S. Ct. 2548 (1986); *Becton Dickinson & Co. v. C.R. Bard, Inc.*, 922 F.2d 792, 795 (Fed. Cir. 1990). Where cross motions are filed, we apply the same standard, adopting a dual perspective. See *Stimsonite Corp. v. Nightline Markers, Inc.*, 33 F. Supp. 2d 703, 705 (N.D. Ill. 1999).

2. The Parties' Cross Motions on Infringement

Patent infringement occurs if a person makes, uses, offers to sell or sells a patented invention within the United States during the term of the patent. 35 U.S.C. § 271(a). Infringement exists if every limitation of the patent claims asserted to be infringed (in this case, all of the claims) is found in the accused process. *SmithKline Diagnostics, Inc. v. Helena Laboratories Corp.*, 859 F.2d 878, 889 (Fed. Cir. 1988). To determine whether infringement has occurred, we must first define as a matter of law the meaning and scope of each patent claim at issue; then we compare the accused process against the properly construed claims to see whether the claim limitations are met either literally or by a substantial equivalent. See *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 387-91, 134 L. Ed. 2d 577, 116 S. Ct. 1384 (1996); *Stimsonite*, 33 F. Supp. 2d at 706-07 (citing *Renishaw PLC*

v. Marposs Societa 'per Azioni, 158 F.3d 1243, 1247-48 (Fed. Cir. 1998)).

To determine the meaning and scope of the patent claims, we look first to the intrinsic evidence — namely, the claims, the specification or written description, and the prosecution history. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). If one of ordinary skill in the art can interpret the intrinsic evidence unambiguously, the court looks no further. *Id.* at 1583.

The principal dispute about claim interpretation in this case is whether Apotex's process requires a "complete" reaction of the active ingredient, enalapril maleate; in other words, whether the patents are limited to those processes in which all of the enalapril maleate is converted to enalapril sodium. Merck argues that the patents require a complete reaction; Apotex argues that they do not. To resolve the dispute, we look first to the claims themselves. *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999) (claim construction begins with the language of the claims). The '780 Patent claims:

> 1. A process of manufacture of a pharmaceutical solid composition comprising enalapril sodium, which process comprises the steps of:
>
> (i)(a) mixing enalapril maleate with an alkaline sodium compound and at least one other excipient, adding water sufficient to moisten, and mixing to achieve a wet mass, or

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(b) mixing enalapril maleate with at least one excipient other than an alkaline sodium compound, adding a solution of alkaline sodium compound in water, sufficient to moisten and mixing to achieve a wet mass; thereby to achieve a reaction without converting the enalapril maleate to a clear solution of enalapril sodium and maleic acid sodium salt in water.

(ii) drying the wet mass, and

(iii) further processing the dried material into tablets.

2. A process as in claim 1 wherein the alkaline sodium compound is selected from the group consisting of sodium hydroxide, sodium carbonate and sodium bicarbonate.

3. A process as in claim 1 or 2 wherein the excipient is lactose.

4. A process as in any of claims 1 to 3 which further comprises addition of a lubricant.

5. A process as in claim 4 wherein the lubricant is a metal stearate.

6. A process as in claim 5 wherein the metal stearate is magnesium stearate.

7. A process as in any of claims 1 to 6 which further comprises the addition of a disintegrant.

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8. A process as in claim 7 wherein the disintegrant is starch.

9. A pharmaceutical solid composition comprising enalapril sodium salt when made by a process according to any of claims 1 to 8. U.S. Patent No. 5,573,780 at col. 5, line 34 – col. 6, line 34.

The '962 Patent's claims are identical in all respects relevant to this lawsuit. *See* U.S. Patent No. 5,690,962, col. 5, line 22 – col. 6, line 27.

Nothing in the claim language calls for a complete reaction. Claim 1(i)(b) — the only claim to specifically mention the reaction — states that the goal of the patented process is "to achieve a reaction without converting the enalapril maleate to a clear solution of enalapril sodium and maleic acid sodium salt in water." U.S. Patent No. 5,573,780, col. 6, lines 10–12. See also U.S. Patent No. 5,690,962, col. 6, lines 5–7 ("to achieve a reaction without converting the enalapril maleate to a clear solution of enalapril sodium and maleic acid in water."). Neither this claim nor any of the other claims speak in terms of a "complete" reaction of the enalapril maleate. Similarly, the specification emphasizes that the reaction is designed to produce stability. See U.S. Patent No. 5,573,780, col. 1, lines 23–67; U.S. Patent No. 5,690,962, col. 1, 24 – col. 2, line 4. If a process that otherwise reads on the claims achieves stability with a reaction that is less than complete, that process would infringe the patents.

The language on which Merck relies to support its claim construction appears in the specification: "It has been found

that so long as the amount of water used is sufficient to render the mass very moist, the acid-base reaction will occur rapidly and will be complete or essentially complete before the drying of the mass in the subsequent drying process is completed." U.S. Patent No. 5,573,780, col. 3, lines 38–42; U.S. Patent No. 5,690,962, col. 3, lines 30–34 (emphasis added). Merck argues that "essentially complete" means "complete." This interpretation is unreasonable because it would require the Court to read "essentially complete" out of the equation. The more reasonable interpretation of that phrase is that it means "virtually complete," that is, "mostly complete but not entirely complete."

Having construed the pertinent claim language, we compare the patented process with the process accused of infringement. During the Canadian infringement litigation, Merck's witness Brian McLeod testified in detail about the process Merck uses to make VASOTEC. McLeod testified that the active ingredient, enalapril maleate, is mixed with "a carrier," "a stabilizer," "a binder" and a "disintegrant." Transcript of McLeod Testimony at 123, 125. Then that mixture is mixed in a "wet granulation"[2] with water to get "a damp mass" or "a wet mass." *Id.* at 127. He clarified that by "damp" or "wet mass" he meant that the mixture was "damp but not gooey." *Id.* He stated that the mass is then spread thinly on trays and placed into a "drying oven" to remove

2. "Wet granulation" is a term used to describe a processing method in pharmaceutical manufacturing in which a solvent (usually water) is used to wet, to the consistency of damp snow or brown sugar, the ingredient being mixed in making a medicinal tablet. Merck's Mem. in Support of Its Summary Judgment Motion on Invalidity, at 3–4.

the moisture. *Id.* at 128. He stated that after the mixture is dried, a lubricant is added — he specifically identified the lubricant as magnesium stearate. *Id.* He stated that the mixture is then formed into tablets. *Id.* at 128-29. Finally, he testified that the goal of the process was to make the tablets in a way that "ensured that each tablet will deliver the exact amount of active ingredient." *Id.* at 125. Thus the only apparent difference between Merck's process, as described by McLeod, and Apotex's process, as described in the claims, is that Merck's process uses "a carrier," "a stabilizer," and "a binder" whereas Apotex's process uses "an alkaline sodium compound and at least one other excipient." If we dig a little deeper, we see that these are really different names for the same things. Interestingly, Apotex's specification uses one of these same words. See U.S. Patent No. 5,573,780, col. 1, 15–18; U.S. Patent No. 5,690,962, col. 1, lines 15–18 ("In order to manufacture pharmaceutical tablets, it is necessary to mix the active ingredient with inactive ingredients which may serve as binders . . . .") (emphasis added). And Merck's product monograph states that, in addition to the active ingredient enalapril maleate, the mix contains the following inactive ingredients or excipients: "lactose, magnesium stearate [the lubricant], sodium bicarbonate and starch [the disintegrant]." Product Monograph for VASOTEC and VASOTEC I.V., at 15 (Oct. 19, 1992). Claim 2 of the patents makes clear that sodium bicarbonate is "an alkaline sodium compound," and Claim 3 of the patents makes clear that lactose is an excipient. U.S. Patent No. 5,573,780, col. 6, lines 16–21; U.S. Patent No. 5,690, 962, col. 6, lines 12–16. Thus, Merck's process reads on all of the claims of the '780 and '962 Patents.

Appendix B

Merck argues that its process does not infringe the patented process because its process "is not 'wet' enough to meet the 'wet mass' limitation" in Claim 1. Merck's Mem. at 12. The argument is undercut substantially by the fact that McLeod described Merck's "wet mass" the same way Sherman described Apotex's "wet mass." But it fails for another reason as well. The claim language is silent as to how much water goes into the mix; the claims do not specify how much water is "sufficient to moisten" or how much water is necessary to "achieve a wet mass." The specification does, however, includes 3 examples of how to achieve the intended result. See U.S. Patent No. 5,573,780, col. 3, line 65 — col. 5, line 32; U.S. Patent No. 5,690,962, col. 3, line 57 – col. 5, line 20. In the first example, the desired "wet mass" was achieved by dissolving 12.2g of sodium hydroxide (an alkaline sodium compound) in 400g of water and then adding that solution to a mixture containing 50g of enalapril maleate and 1660g of lactose monohydrate powder (the other excipient). *Id.* at col. 4, lines 5–31. In the second example, the desired "wet mass" was achieved by dissolving 32.3g of sodium carbonate in 400g of water and then adding that solution to a mixture containing 100g of enalapril maleate, 1600g of lactose monohydrate powder and 5g of a colouring agent. *Id.* at col. 4, lines 35–67. In the third example, the desired "wet mass" was achieved by adding 400g of water to a mixture containing 50g of enalapril maleate, 25.6g of sodium bicarbonate and 1650g of lactose monohydrate powder. *Id.* at col. 5, lines 1–32. Merck's process uses a much lower proportion of water to the enalapril maleate compound than is specified in the specification's examples. The wet granulation in Merck's process is generated by mixing about 12% water by weight as compared with the dry ingredients,

whereas, according to Merck, if we did the math in the above examples, we would find that Apotex's process uses at least 23% water by weight. Based on this fact, Merck argues that its process cannot literally infringe the patents. We disagree.

Merck's noninfringement argument would require the Court to read a limitation from the written description into the claims, something we are not permitted to do under the law. *See Vitronics*, 90 F.3d at 1582. It is true that if a particular term in need of definition is used but not defined in the claims, we may look to the specification for such a definition. *See Renishaw*, 158 F.3d at 1248. But even if we were to find that the terms "sufficient to moisten" and "wet mass" — used but not defined in Claim 1 — open the door for us to look at the specification for elucidation of those phrases, the specification clearly states that it is not intended to confine the patents' scope. Certainly the examples given clarify what amount of water may be "sufficient to moisten" and what combination of ingredients may create a "wet mass." The specification expressly states, however, that the examples disclosed are "intended to be illustrative but not limiting of the invention." U.S. Patent No. 5,573,780, col. 3, lines 65–67; U.S. Patent No. 5,690,962, col. 3, lines 54–56. The examples are just that — examples; they do not foreclose the possibility that other proportions would also achieve the intended result. Thus, the fact that Merck uses different amounts of water or different amounts of enalapril maleate or different amounts of any of the other ingredients is of little consequence.

There are no material issues of fact on the infringement issue; the parties' respective processes are what they are.

Based on the facts, as described above, the Court finds that Merck's process literally infringes Apotex's patents, that Apotex is entitled to judgment as a matter of law and that Merck is not. Of course, invalidity is a defense to infringement. *See* 35 U.S.C. § 282 (alleged infringer who can show that the patent asserted against him or her is invalid cannot be liable for infringement); *Ever-Wear, Inc. v. Wieboldt Stores, Inc.*, 427 F.2d 373, 376 (7th Cir. 1970) (only valid patents may be infringed). So we must still consider Merck's motion for summary judgment that the patents are invalid.

2.[sic] Merck's Motion for Summary Judgment that Apotex's Patents are Invalid

This is not the first time Merck has asked the Court to hold Apotex's patents invalid. Merck previously sought summary judgment on the same issue, though on different grounds. In its earlier motion, Merck argued that it was entitled to summary judgment under 35 U.S.C. § 102(f) because Sherman derived the subject matter of the patents in suit from Merck's process (in other words, Sherman was not the original inventor; Merck was). Subsection (f) provides that a person shall be entitled to a patent unless "he did not himself invent the subject matter sought to be patented." It is a derivation provision, which provides that one may not obtain a patent on that which is obtained — through public information or through communications with the prior inventor — from someone else whose possession of the subject matter is inherently "prior." *See Oddzon Products, Inc. v. Just Toys, Inc.*, 122 F.3d 1396, 1401 (Fed. Cir. 1997). According to Magistrate Judge Ashman, to whom the case had been referred, both parties agreed "that Merck was the

first to conceive the subject matter claimed in the '780 Patent" and that the only question for him to decide was whether Merck's conception was communicated to Dr. Sherman "in a manner that would enable one of ordinary skill in the art to make stable enalapril tablets." Report and Recommendation at 9. Judge Ashman recommended that the Court deny summary judgment because he found an issue of fact as to whether Dr. Sherman concluded on his own that Merck used a wet granulation process to make its tablets (as Sherman claimed) or whether Sherman learned about the process through some communication from Merck (as Merck claimed). *Id.* at 11. The parties did not object to Judge Ashman's recommendation, and Judge Marovich, to whom this case was previously assigned, accepted it and denied summary judgment. This time around, Merck is attempting to avoid the fact issues identified by Judge Ashman by arguing that it is entitled to summary judgment under 35 U.S.C. § 102(g), which does not require that the second inventor actually know about the prior invention. *See E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 1437 (Fed. Cir.), *cert. denied*, 488 U.S. 986, 102 L. Ed. 2d 572, 109 S. Ct. 542 (1988).

Before deciding whether Apotex's patents are invalid under 35 U.S.C. § 102(g), we must quickly address Apotex's argument that this section "requires acts in the United States" and does not apply because Merck's public disclosure of its process took place in Canada. Section 102(g) provides as follows:

> [a] person shall be entitled to a patent unless . . . before the applicant's invention thereof the

> invention was made in this country by another who had not abandoned, suppressed, or concealed it.

By its plain language, the statute requires only that the process is invented in the United States, not that the process be employed or disclosed in the United States after being invented. *See also Paulik v. Rizkalla*, 760 F.2d 1270, 1278 (Fed. Cir. 1985) (Rich, J., concurring). Judge Rich, who was intimately involved in drafting § 102(g), explained that one of the earlier versions of the statute required more of the inventor's activities to occur in the United States; specifically, it required that the prior invention be "made in this country by another who had not abandoned it and who was using reasonable diligence in this country in reducing it to practice. . . ." *Paulik*, 760 F.2d at 1278 (Rich, J., concurring). That language was taken out in favor of the current version, which requires only that the invention be made in this country and not abandoned, suppressed or concealed — in any country. *Id.* The undisputed record evidence shows that Merck's scientists invented the accused process and reduced it to practice at Merck's lab in West Point, Pennsylvania. In short, section 102(g) does apply, and we now consider the consequences of that application.

A patent is presumed to be valid. 35 U.S.C. § 282. The party challenging the patent's validity must show, by clear and convincing evidence, that the patent is invalid. *Checkpoint Systems, Inc. v. United States International Trade Commission*, 54 F.3d 756, 761 (Fed. Cir. 1995); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1375 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947, 94 L. Ed. 2d 792, 107 S. Ct. 1606 (1987). Thus, Merck must prove by

clear and convincing evidence that Apotex's patents are invalid. Because it is asserting invalidity under 35 U.S.C. § 102(g), Merck must prove by clear and convincing evidence that: (1) Merck invented its process within the United States before Sherman invented his process; and (2) Merck neither abandoned, suppressed nor concealed its invention.

The parties agree that Merck invented the allegedly infringing process long before Sherman conceived of the idea. Apotex admits that Merck's scientists developed the process at its West Point, Pennsylvania facility in the early 1980s. Apotex further admits that Sherman conceived of the idea for the patented process some time after March 30, 1994 and before April 19, 1994 and that his invention was first reduced to practice on April 19 or within a few days thereafter. Thus the first element of Merck's defense is satisfied. Moreover, the evidence does not suggest, and Apotex does not contend, that Merck abandoned the process; indeed, the evidence establishes that Merck has been using its process continuously since at least 1983. Thus, under 35 U.S.C. § 102(g), the only question for the Court is whether Merck suppressed or concealed its invention at the time Sherman allegedly conceived of the process.

The purpose of our patent law is to "advance the useful arts" and "technological innovation"; "to encourage innovation and its fruits." *Paulik*, 760 F.2d at 1276. "As implemented by the patent statute, the grant of the right to exclude [others from making a particular product or using a particular process] carries the obligation to disclose the workings of the invention, thereby adding to the store of knowledge without diminishing the patent-supported

incentive to innovate." *Id.* Section 102(g) fits into this scheme by encouraging "prompt public disclosure of an invention by penalizing unexcused delay or failure of a first inventor to share the 'benefit of the knowledge of [the] invention' with the public after the invention has been completed." *Checkpoint Systems*, 54 F.3d at 761 (quoting *Paulik*, 760 F.2d at 1280 (Rich, J., concurring)). Priority under this section goes to "the 'first' inventor in law, regardless of fact." *Paulik*, 760 F.2d at 1281 (Rich, J., concurring). To determine priority, we ask not only who first conceived of the invention, but also "whether the facts as to what was or was not done lead to the legal conclusion of 'suppressed, or concealed.' " *Id.* at 1280. See also *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1567 (Fed. Cir. 1996). Suppression or concealment may be intentional, as when the prior inventor "designedly, and with the view of applying it indefinitely and exclusively for his own profit, withholds his invention from the public." *Paulik*, 760 F.2d at 1273 (quoting *Kendall v. Winsor*, 62 U.S. (21 How.) 322, 328, 16 L. Ed. 165 (1858)). Or suppression or concealment may be inferred from the facts of the particular case, where for example, an inventor delays "too long" in filing a patent application. *Fujikawa*, 93 F.3d at 1565 (citing *Paulik*, 760 F.2d at 1273).

In *Paulik*, the Federal Circuit inventoried the decisions involving suppression or concealment under section 102(g). After briefly discussing the cases, the court summarized the law as follows:

> The decisions applying section 102(g) balanced the law and policy favoring the first person to make an invention, against equitable

> considerations when more than one person had made the same invention: in each case where the court deprived the de facto first inventor of the right to the patent, the second inventor had entered the field during a period of either inactivity or deliberate concealment by the first inventor.

760 F.2d at 1275.

This case simply does not fit that mold. Certainly Apotex cannot accuse Merck of inactivity; by 1994, when Sherman conceived of the patented process, Merck had been continuously using its process to make VASOTEC tablets and it had been selling its product in the commercial markets for more than a decade. In 1993 alone Merck had more than $150 million in VASOTEC sales.

Nor do the facts of this case suggest that Merck deliberately suppressed or concealed its invention. The test for suppression or concealment under § 102(g) is whether within a reasonable time after completion of the invention, the prior inventor took steps to make its invention publicly known. *Levi Strauss & Co. v. Golden Trade, S.r.L.*, 1995 U.S. Dist. LEXIS 4899, Nos. 92 Civ. 1667 (RPP), 90 Civ. 6291 (RPP), 90 Civ. 6292 (RPP), 1995 WL 710822, at *18 (S.D.N.Y. Dec. 1, 1995) (citing *International Glass Co. v. United States*, 187 Ct. Cl. 376, 408 F.2d 395, 403 (Ct. Cl. 1969)). *See also Checkpoint Systems*, 54 F.3d at 763 (no suppression or concealment if public promptly received the benefit of knowledge of first inventor's product). "Possible steps [to make the invention publicly known] include filing a patent application, describing the invention in a publicly

disseminated document, and using the invention publicly." *Levi Strauss*, 1995 WL 710822, at *18. Merck prepared and distributed widely its product monograph, which describes its VASOTEC tablets and gives a list of the ingredients used to make the tablets, as well as the chemical name, the structural formula, the molecular weight and the composition. Merck distributed more than 30,000 copies of the monograph in 1993 alone. Merck also described its product in the Dictionnaire Vidal, a French language pharmaceutical dictionary, and it disclosed the process for making VASOTEC tablets at the Canadian infringement trial — significantly, without seeking any kind of a protective order or other means of limiting disclosure of the process to the general public. Merck also used its invention publicly, selling the fruits of the invention in mass quantities in the commercial markets. Taken together, these facts clearly and convincingly establish that Merck did not intentionally suppress or conceal its invention.

In opposition to Merck's motion, Apotex has argued that Merck suppressed and concealed its invention to keep others from breaking into the enalapril maleate tablet market. Yet, Apotex offers no evidence to back up this claim. Apotex can point only to the fact that Merck never filed a patent application, and this alone is not sufficient to support a finding of deliberate suppression or concealment. *See E.I. du Pont*, 849 F.2d at 1437 (failure to file patent application does not by itself constitute suppression or concealment).

Apotex argues that the way in which Merck disclosed its process was not sufficient to show a person of ordinary skill in the art how to duplicate the process. The Court

disagrees. As described above, Brian McLeod's testimony and the accompanying videotape explained the process in detail. And to the extent McLeod failed to specifically name any of the ingredients used in the process, Merck's product monograph and the Dictionnaire Vidal were available to fill in any blanks. Apotex also argues that Merck's evidence of disclosure does not satisfy § 102(g) because the disclosure was not made in a single written publication. But § 102(g) does not require disclosure at all, let alone disclosure in a particular form. It requires, as we have already noted, that the invention not be abandoned, suppressed or concealed. Written public disclosure is just one possible way to demonstrate that an invention has neither been abandoned, suppressed or concealed.

Finally, Apotex argues that Merck lied to the Food & Drug Administration in its new drug application (NDA) for Tablets VASORIL (Enalapril Maleate, MSD) dated September 15, 1983. Apotex argues that in section 7 of the NDA, Merck listed the starting ingredients for these tablets when it should have listed the ingredients in the final composition of the tablets. Merck did this, according to Apotex, to hide the fact that a reaction occurs in the tableting process because, if Merck had disclosed the end product's ingredients, the FDA "would have been alerted to the fact that a chemical reaction had occurred and [the FDA reviewer] would have probed Merck as to the tableting process." Apotex's Mem. in Opposition to Merck's Summary Judgment Motion, p. 15. Even if we accept Apotex's allegations as true, we fail to see how this bears on the issue of suppression or concealment. To the extent Apotex is implying that in 1983 Merck was hiding the fact that its process involved reacting

enalapril maleate to form a more stable enalapril sodium compound, that time frame is irrelevant. The relevant time frame for purposes of § 102(g) is when the later inventor conceives of his invention — in this case, some time between March 30, 1994 and April 19, 1994. By that time, Merck had fully disclosed the ingredients and the process. Plus, even Apotex's witnesses agreed that any chemist who knew the ingredients and knew that the process involved adding water to the mix would automatically know that a reaction of the enalapril maleate occurred. Dr. Richard McKeag, a scientist who worked with Dr. Sherman at Apotex Canada, testified that "it was so simple that it was obvious; any chemist would know that, if you added bicarbonate or carbonate to a solution containing enalapril maleate, you would get the formation of the salt. You would get a chemical reaction to form a salt." McKeag Deposition Transcript, at 41. He also testified that "if you take sodium bicarbonate and put it into water and you have enalapril maleate in the same solution, it will react virtually spontaneously and irreversibly to form a new compound, to form enalapril sodium and disodium maleate." *Id.* at 46. Finally, he testified that "any chemist who looks at enalapril maleate would automatically assume its going to react with three moles of sodium bicarbonate . . . if they are placed together in solution or in slurry or whatever, anything wet." *Id.* at 47. In short, what Apotex characterizes as "rank suppression and concealment" would not have fooled anyone — or at least anyone with a fundamental knowledge of chemistry.

Under the standards articulated above, Merck is both the first inventor in fact and the first inventor in law, and principles of equity, when viewed against the facts of this

particular case, require the Court to give priority to Merck. Accordingly, the Court finds that Apotex's patents are invalid under 35 U.S.C. § 102(g).

CONCLUSION

For the reasons explained above, the Court finds that Merck's process for making VASOTEC enalapril maleate tablets literally infringes U.S. Patent No. 5,573,780 and U.S. Patent No. 5,690,962. But the Court further finds that Merck has a defense to the literal infringement — namely invalidity under 35 U.S.C. § 102(g) — because Merck invented its process for making VASOTEC in the United States before Sherman invented the process covered in the '780 and '962 Patents and neither abandoned, suppressed nor concealed that process. Accordingly, the Court denies Merck's motion for summary judgment of noninfringement, grants Apotex's motion for summary judgment of infringement and grants Merck's motion for summary judgment that the patents in suit are invalid. Judgment will enter in favor of Merck and against Apotex.

Dated: January 20, 2000

MATTHEW F. KENNELLY
United States District Judge

APPENDIX C — MEMORANDUM OPINION AND ORDER OF THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS, EASTERN DIVISION DATED AND DECIDED MARCH 17, 2000 AND DOCKETED MARCH 23, 2000

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS,
EASTERN DIVISION

Case No. 96 C 7375

APOTEX CORP.,

Plaintiff,

v.

MERCK & CO., INC.,

Defendant.

March 17, 2000, Decided
March 23, 2000, Docketed

MEMORANDUM OPINION AND ORDER

MATTHEW F. KENNELLY, District Judge:

On January 20, 2000 the Court issued an opinion granting summary judgment to the defendant, Merck & Co. *See Apotex Corp. v. Merck & Co., Inc.*, 2000 U.S. Dist. LEXIS 641, No. 96 C 7375, 2000 WL 97582 (N.D. Ill. Jan. 25, 2000). The Court held that Apotex's '780 and '962 patents are invalid

under 35 U.S.C. § 102(g) because Merck invented the patented process in the United States before Apotex and did not abandon, suppress or conceal its process. Apotex has asked the Court to reconsider this ruling. Familiarity with the Court's January 20 opinion is assumed.

First, Apotex argues that the Court was wrong to consider evidence from the Canadian litigation and wrong to combine disclosures to find that Merck neither suppressed nor concealed its invention. As before, Apotex cites no authority for these propositions. The Court will therefore rely on its earlier analysis: the test for suppression or concealment under § 102(g) is whether within a reasonable time after completion of the invention, the prior inventor took steps to make its invention publicly known. *See Levi Strauss & Co. v. Golden Trade, S.r.L.*, 1995 U.S. Dist. LEXIS 22145, Nos. 92 Civ. 1667 (RPP), 90 Civ. 6291 (RPP), 90 Civ. 6292 (RPP), 1995 WL 710822, at *18 (S.D.N.Y. Dec. 1, 1995) (*citing International Glass Co. v. United States*, 187 Ct. Cl. 376, 408 F.2d 395, 403 (Ct. Cl. 1969)). This section does not limit how an inventor may accomplish this, and we see nothing in the law to preclude us from considering evidence adduced in a foreign country or from considering various disclosures in combination to answer the question. *See E.I. DuPont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 1436 n.5 (Fed. Cir. 1988) (court considered filing of foreign patent application in concluding that invention was neither suppressed nor concealed); *Application of Hilmer*, 53 C.C.P.A. 1288, 359 F.2d 859, 878 (C.C.P.A. 1966) ("acts in a foreign country are not to defeat the rights of applicants for patents, except as applicants may become involved in priority disputes.") (emphasis added).

Appendix C

Second, Apotex argues that the disclosures on which the Court relied did not disclose a key part of Merck's process: the chemical reaction between the active ingredient enalapril maleate and the sodium bicarbonate. The Court addressed this issue in its January 20 opinion, concluding that anyone with a working knowledge of chemistry would know that if enalapril maleate and sodium bicarbonate are present, a reaction occurs — Apotex's own witnesses, including Dr. Bernard Sherman, admitted as much.

Apotex argues that the Court asked the wrong question; rather than asking whether a reaction was disclosed because of the presence of these ingredients, we should have asked whether the evidence disclosed that these ingredients were actually mixed together in the process. Apotex argues that the Canadian litigation evidence, even when read in combination with the product monograph and Dictionnaire Vidal entry, did not disclose the presence of sodium bicarbonate in the initial mix; rather they disclosed the presence of sodium bicarbonate in the end product that results when the process is complete. Thus, according to Apotex, the fact that the product monograph lists sodium bicarbonate would not allow a chemist — or anyone else — to conclude that a chemical reaction between these two ingredients necessarily occurred. At best, Apotex argues, whether the product monograph lists the chemical make-up of Merck's tablets or the ingredients that go into the process to make the tablets is a question of fact that should have precluded summary judgment.

Contrary to Apotex's assertion, the record evidence, including the new evidence presented with Apotex's motion

to reconsider, does not support a finding that Merck concealed or suppressed the presence of sodium bicarbonate in its process. Apotex cites the declarations of Dr. Bernard Sherman, Dr. Stanley Scheindlin and Jens T. Carstensen to support its argument that the monograph concealed or suppressed the existence of sodium bicarbonate in the process. First, this substantially misreads Dr. Sherman's declaration. Sherman did not say that the monograph could be read to say that sodium bicarbonate was present in the final tablet rather than the mixing process; he actually said that interpreting the product monograph this way made absolutely no sense: "As can be seen, [the product monograph] stated that 'each tablet contains non-medicinal ingredients including . . . sodium bicarbonate.' I knew this could not be true since my 1990 experiments established that a tablet with enalapril maleate and sodium bicarbonate was unacceptably unstable." Sherman Declaration, P11 (attached as Exhibit A to Apotex's Mem. of Law Opposing Merck's Motion for Summary Judgment under 35 U.S.C. § 102(g)). In light of Sherman's admission that a stable tablet could not contain enalapril maleate and sodium bicarbonate, it is difficult to imagine that he ever believed sodium bicarbonate was present in the end product and not in the mixing process. With the public disclosure in 1994 that the process involved wet granulation, such a belief would have been totally unfounded.

Nor do the declarations of Scheindlin and Carstensen reveal an issue of fact on this score. Carstensen said that he believed pharmaceutical professionals would read the monograph to mean that the listed ingredients (including the sodium bicarbonate) were present in the tablets; Scheindlin

stated that he believed health professionals and the general public could read the monograph to mean that the listed ingredients (including the sodium bicarbonate) were present in the tablets. Even if we accept these statements as true, they do not create an issue of fact on concealment or suppression, *see Wolverine World Wide, Inc. v. Nike, Inc.*, 38 F.3d 1192, 1199 n.5 (Fed. Cir. 1994) ("contradictory litigation-induced pronouncements are insufficient to raise a genuine issue of material fact"), especially in light of the fact that Sherman's own declaration totally undermines the argument that the monograph concealed or suppressed anything.

Apotex argues that the Court's interpretation of the monograph as disclosing the list of ingredients that go into the mix "sub silentio overrules Magistrate Judge Ashman's findings of a genuine issue of fact, previously adopted by the Court." Mem. In Support of Motion for Reconsideration, p. 6. This argument misreads Judge Ashman's ruling: he did not find an issue of fact as to whether the product monograph disclosed the ingredients in the process or the ingredients in the tablet; rather, he found issues of fact as to whether Sherman discovered that Merck used a wet granulation process from the product monograph or from some other independent source, and as to whether the product monograph would enable one of ordinary skill in the art to conclude that Merck's tablets were made using a wet granulation method. See Report and Recommendation, pp. 10-11. Neither of these issues were material to this Court's analysis because: (1) what Sherman knew when he "invented" his process, though relevant for purposes of 35 U.S.C. § 102(f) (the statutory basis for the motion before Judge Ashman), was immaterial

for purposes of § 102(g); and (2) whether or not the product monograph disclosed the wet granulation method, McLeod clearly disclosed that the process used this method when he testified in the Canadian litigation (Judge Ashman could not consider the Canadian litigation evidence because Sherman said he wasn't there to hear it, which though relevant for purposes of the derivation analysis under § 102(f), is immaterial under § 102(g)).

The record evidence before this Court clearly established that enalapril maleate, sodium bicarbonate and other excipients were combined through wet granulation to make the Vastotec [sic] tablets.

Apotex also argues that a Canadian decision, issued the day after this Court issued its opinion, in an action related to the Canadian litigation discussed in the Court's January 20 opinion, supports its argument that the product monograph lists the ingredients in the tablet, not the ingredients in the mixing process. The new Canadian opinion does not support Apotex's argument: the Canadian court found that Nu-Enalapril, a competitor to Vasotec manufactured by Nu-Pharm, Inc. (another company to which Dr. Bernard Sherman is connected), infringed Vasotec because it contains enalapril maleate. The opinion says nothing about sodium bicarbonate. So the Court is left with the disclosure of the process through McLeod's testimony in the Canadian litigation in 1994, through the product monograph and through the Dictionnaire Vidal entry, plus the fact that Merck has been using the process commercially since at least 1983. The Court remains convinced that these disclosures clearly and convincingly prove Merck neither suppressed nor concealed its invention.

Appendix C

At the hearing on Apotex's motion to reconsider, Merck argued that § 102(g) does not require disclosure of the invention to the public; it simply requires that the invention is neither concealed nor suppressed. The Court quite agrees and tried to make this point clear in its January 20 opinion. *See Apotex Corp.*, 2000 U.S. Dist. LEXIS 641, No. 96 C 7375, 2000 WL 97582, at *8. *See also E.I. DuPont*, 849 F.2d at 1437 ("Nor does § 102(g) contain a 'known to the art' requirement apart from the requirement of no abandonment, suppression or concealment."). Thus, whether Merck made its invention "known to the art" or publicly known is immaterial[1] as long as Merck did not otherwise suppress or conceal its invention. As explained above and in the Court's earlier opinion, it did not.

For these reasons, Apotex's motion for reconsideration is denied, as is Merck's motion to strike Apotex's exhibits. Apotex has until March 31, 2000 to respond to Merck's Bill of Costs.

Dated: March 17, 2000

MATTHEW F. KENNELLY
United States District Judge

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1. Having said that, the Court notes that Apotex's new exhibits demonstrate that at least one member of the public, Joseph Schwartz, professor of pharmaceutics and director of industrial pharmacy research at the University of Sciences in Philadelphia, was present in court when McLeod described the process for making Vasotec. *See* Apotex's Mem. In Support of its Motion for Reconsideration, Exhibit O, pp. 55–56.

APPENDIX D — ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT DENYING PETITION FOR REHEARING DATED, DECIDED AND FILED AUGUST 2, 2001

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

00-1272

APOTEX USA, INC.,

Plaintiff-Appellant,

v.

MERCK & CO., INC.,

Defendant-Appellee.

August 2, 2001, Decided
August 2, 2001, Filed

DECISION WITHOUT PUBLISHED OPINION

ORDER

A combined petition for panel rehearing and for rehearing en banc having been filed by the APPELLANT, and a response thereto having been invited by the court and filed by the APPELLEE, and the petition for rehearing having been referred to the panel that heard the appeal, and thereafter the petition for rehearing en banc and response having been referred to the circuit judges who are in regular active service,

Appendix D

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for panel rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the petition for rehearing en banc be, and the same hereby is, DENIED.

The mandate of the court will issue on August 9, 2001.

Circuit Judge GAJARSA did not participate in the vote.

Dated: August 2, 2001

APPENDIX E — UNITED STATES PATENT NO. 5,573,780

[Omitted here but submitted separately as Lodging]

APPENDIX F — UNITED STATES PATENT NO. 5,690,962

[Omitted here but submitted separately as Lodging]

APPENDIX G — *MERCK & CO., INC. v. APOTEX INC.*, 59 C.P.R. (3d) 133 (1994)

[Omitted here but submitted separately as Lodging]

APPENDIX H — *MERCK & CO. v. NU-PHARM INC.*, 4 C.P.R. (4th) 464 (2000)

[Omitted here but submitted separately as Lodging]

APPENDIX I — DECLARATION OF JENS T. CARSTENSEN DATED JULY 10, 1998

[Omitted here but submitted separately as Lodging]

APPENDIX J — DECLARATION OF STANLEY SCHEINDLIN, D.Sc. DATED JULY 12, 1998

[Omitted here but submitted separately as Lodging]

APPENDIX K — DECLARATION OF DR. BERNARD C. SHERMAN DATED JULY 13, 1998

[Omitted here but submitted separately as Lodging]

APPENDIX L — SUPPLEMENTAL DECLARATION OF DR. BERNARD C. SHERMAN DATED JULY 13, 1998

[Omitted here but submitted separately as Lodging]

APPENDIX M — DECLARATION OF STANLEY SCHEINDLIN, D.Sc. DATED DECEMBER 14, 1999

[Omitted here but submitted separately as Lodging]

APPENDIX N — MEMORANDUM TO ROBERT MONAGHAN FROM WILLIAM HITCHINGS RE ENALAPRIL MALEATE – ITALY DATED MAY 10, 1985

[Omitted here but submitted separately as Lodging]

Supreme Court, U.S.
FILED
JAN 22 2002
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(7)

No. 01-847

In the Supreme Court of the United States

APOTEX USA, INC.,
Petitioner,

v.

MERCK & CO., INC.,
Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF IN OPPOSITION

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33pp

QUESTION PRESENTED

Respondent Merck & Co., Inc. discovered and began using a formulation process to make a very successful high blood pressure medication, known as VASOTEC®. Merck has used its process since at least 1983 and has sold VASOTEC® since 1986. After Merck disclosed its manufacturing process to Apotex Canada in open court during Canadian patent litigation in 1994, Petitioner Apotex USA prosecuted and obtained two U.S. patents to cover Merck's process, and then sued Merck for allegedly infringing those patents.

Not surprisingly, the district court granted summary judgment that Merck was the prior inventor of the claimed processes and invalidated Apotex USA's patents under 35 U.S.C. § 102(g), which prevents patents being obtained on inventions previously made by another who had not abandoned, suppressed, or concealed such invention. The Federal Circuit affirmed, holding that Merck's testimony in open court and its other public disclosures provided clear and convincing evidence that Merck made knowledge of its earlier invention of the accused process available to the public and had not suppressed or concealed it. Based on the above, the only question presented by this case is:

Whether the Court of Appeals correctly affirmed the district court's summary judgment that the Petitioner's patents were invalid under 35 U.S.C. § 102(g), where Merck discovered, used, and disclosed the patented process years before Petitioner's named inventor even "conceived" of his alleged invention days after Merck's process was disclosed in open court and where Petitioner's remaining arguments distort the statutory language, mischaracterize the lower court and foreign court proceedings, and advance new arguments not supported by the statute or the record?

RULE 29.6 STATEMENT

No parent or publicly held company owns 10% or more of Respondent, Merck & Co., Inc.'s, stock.

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In the Supreme Court of the United States

No. 01-847

APOTEX USA, INC.,
Petitioner,

v.

MERCK & CO., INC.,
Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF IN OPPOSITION

Respondent Merck & Co., Inc. ("Merck") respectfully urges this Court to deny the petition for writ of certiorari to review the decision of the United States Court of Appeals for the Federal Circuit. Having lost on summary judgment, on rehearing, on appeal (unanimously), and again on rehearing, the petitioner, Apotex USA, Inc. ("Petitioner" or "Apotex USA"), has not presented a single valid basis upon which this Court should grant certiorari. Instead, Apotex USA concocts "important questions of Federal law" and attributes its loss to outlandish claims of fraud by Merck and of incredulous ineptitude by both the Court of Appeals and the District Court. However, the lower courts correctly held that the undisputed evidence in this particular case clearly demonstrated that Merck's accused process had been invented by Merck long before Apotex USA tried to patent it, so that Apotex USA's asserted patents were invalid as a matter of law under 35 U.S.C. § 102(g).

OPINIONS BELOW

The Federal Circuit's decision for which Petitioner seeks review by this Court is *Apotex USA, Inc. v. Merck & Co., Inc.*, 254 F.3d 1031 (Fed. Cir. 2001). Pet. App. A, 1a-17a. The Federal Circuit's order denying Petitioner's petition for panel rehearing and rehearing en banc is reproduced at Pet. App. D, 46a. The opinions of the district court on summary judgment, Pet. App. B, 18a-38a, and denying reconsideration, Pet. App. C, 39a-45a, are not officially reported, but can be found at *Apotex Corp. v. Merck & Co., Inc.*, 2000 WL 97582 (N.D. Ill. Jan. 25, 2000) and *Apotex Corp. v. Merck & Co., Inc.*, 2000 WL 656670 (N.D. Ill. Mar. 17, 2000), respectively.

JURISDICTION

The district court had jurisdiction under 28 U.S.C. § 1338(a). The Federal Circuit, whose jurisdiction was based on 28 U.S.C. § 1295(a)(1), entered the judgment of which Apotex seeks review in its petition on June 8, 2001. Pet. App. A, 1a. The Federal Circuit denied rehearing on August 2, 2001. Pet. App. D at 46a-47a. Apotex invokes the jurisdiction of this Court under 28 U.S.C. § 1254(1).

The petition for certiorari was filed on October 31, 2001 and docketed on December 6, 2001. Upon Merck's request, this Court extended Merck's deadline for filing a response until January 22, 2002.

CONSTITUTIONAL AND STATUTORY POSITIONS INVOLVED

35 U.S.C. § 102(g) is the only constitutional or statutory provision that the Court would need to consider to resolve this case. As explained herein, Apotex USA's

arguments fall into three categories: 1) disagreement with fact finding and proper application of legal principles to those facts; 2) an attempt to manufacture an issue of first impression by baselessly attempting (in direct contradiction to federal statute and Federal Circuit precedent) to read a requirement into 35 U.S.C. § 102(g) that a person challenging the validity of a patent on the basis of section 102(g) prior art must prove that the United States public was aware of such art following a suppression or concealment; and 3) a claim that Merck did not satisfy, in the context of a summary judgment motion, 35 U.S.C. § 282, despite the fact that a) Apotex USA did not raise this issue below,[1] thereby waiving it, and b) the provision of section 282 in question only applies in the context of trial.

STATEMENT OF THE CASE

I. Procedural History

In 1991, Merck and its Canadian subsidiary, Merck Frosst Canada, Inc. ("Merck Frosst"), filed a Canadian lawsuit against Apotex USA's Canadian affiliate, Apotex, Inc. ("Apotex Canada"). Apotex Canada was infringing a Canadian patent owned by Merck Frosst that covered an active ingredient in an anti-hypertension medication known as "enalapril maleate." Merck has made hypertension medication utilizing the active ingredient, enalapril maleate, under the name, VASOTEC®, since 1983. In 1994, during the course of the Canadian litigation, Merck played, in open

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[1] Apotex USA first attempted to raise an issue about Merck's compliance with section 282, after changing lead counsel, in a motion for leave to file supplemental authority in support of its petition for a rehearing. The Federal Circuit properly denied Apotex USA's motion and rejected Apotex USA's supplemental brief, *sua sponte*, presumably because it raised new issues not presented previously.

court, a silent videotape of one of its employees demonstrating Merck's process for formulating VASOTEC® tablets. Brian McLeod, Merck Frosst's Vice-President of marketing at the time narrated the tape and explained Merck's formulation process.[2] Dr. Bernard Sherman, President of Apotex Canada, at the time, attended at least portions of the Canadian trial.

After Merck disclosed its formulation process in detail, Dr. Sherman filed applications for U.S. patent Nos. 5,573,780 ("the '780 patent") and 5,690,962 ("the '962 patent") (collectively "the Apotex USA patents"), which he assigned to Apotex USA. When the Apotex USA patents issued, Apotex USA brought the present case against Merck in the United States District Court for the Northern District of Illinois for Merck's alleged infringement of the Apotex USA patents.

Merck filed a motion for summary judgment of invalidity under 35 U.S.C. § 102(f) based upon Merck's contention that Dr. Sherman derived the invention claimed in the Apotex USA patents from Merck by filing the applications for the Apotex USA patents based upon information that he learned about Merck's process for formulating VASOTEC® tablets from Merck in the Canadian litigation. Pet. App. B, 29a-30a. The district court denied that motion on the basis of issues of material fact, because Dr. Sherman claimed that he did not attend trial on the particular day when Merck disclosed its formulation process in open court to Apotex Canada's litigation team and anyone

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[2] *See* transcript of March 28, 1994 of Brian McLeod trial testimony in *Merck & Co., Inc. et al. v. Apotex, Inc.* in the Federal Court of Canada ("McLeod Canadian Tr. Tran."), Trial Division, which is of record and can be found at A251-A257 in the Joint Appendix before the Federal Circuit in this case.

else who was present in the courtroom and that he did not learn the details of Merck's public disclosure later. *See* Pet. App. B, 30a; Joint Appendix to Federal Circuit Appeal, A77-A97.

Later, the parties filed cross motions on the issue of infringement, and Merck filed a motion for summary judgment of invalidity of the two Apotex USA patents under 35 U.S.C. § 102(g). The district court granted Apotex USA's motion for summary judgment of infringement and Merck's motion for summary judgment of invalidity, and denied Merck's motion for summary judgment of noninfringement. Pet. App. B, 18a-38a. The basis of Merck's section 102(g) motion was that, to the extent that Merck's process infringed the Apotex USA patents, that process was invalidating prior art to the Apotex USA patents because the Merck process predated Apotex USA's alleged conception of the process claimed in the Apotex USA patents by many years. Apotex USA filed a motion for reconsideration of the district court's summary judgment, which the district court denied. Pet. App. C, 39a-45a.

Apotex USA appealed the district court's summary judgment of invalidity of both Apotex USA patents under section 102(g) to the Federal Circuit, and the Federal Circuit affirmed the decision of the district court. Pet. App. A, 1a-17a. Apotex USA sought a panel rehearing and a rehearing en banc, which the Federal Circuit denied. Pet. App. D, 46a. The Federal Circuit also denied *sua sponte* a motion by Apotex USA seeking leave to file supplemental authority.

II. Merck's Disclosures Proved that No Abandonment, Suppression or Concealment Was Possible as of the Time of Dr. Sherman's Alleged Conception

Merck published the ingredients used in manufacturing its VASOTEC® tablets at least as early as the release of its 1992 VASOTEC® Product Monograph (the "Product Monograph"), Pet. App. A, 3a, which was publicly available since October 1992, and throughout 1993 and 1994. Pet. App. A, 3a, 16a; *see also* Pet. App. B, 35a. More than 30,000 copies of the Product Monograph were distributed in 1993 alone. Pet. App. A, 3a; Pet. App. B, 35a. Dr. Sherman even admitted that he had learned of Merck's ingredients from the Product Monograph. Pet. App. A, 16a-17a. Moreover, Merck had also published the ingredients used in manufacturing its RENITEC® enalapril tablets (i.e., the trademark used for VASOTEC® tablets sold in certain foreign countries) as early as the 1988 edition of the *Dictionnaire Vidal*, a French pharmaceutical reference publication.[3] Pet. App. A, 3a, 16a.

The steps of Merck's process were the subject of public testimony at the 1994 trial in the Canadian litigation. On March 28, 1994, Mr. Brian McLeod, then Vice-President of Marketing for Merck Frosst, presented a tutorial in open court and disclosed Merck's process for manufacturing VASOTEC® tablets. Pet. App. A, 3a, 16a; Pet. App. B, 20a, 25a-26a, 35a-36a. The specific ingredients used in the process were already published in the Product Monograph.

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[3] The *Dictionnaire Vidal* disclosure, which like the Product Monograph disclosed the ingredients of Merck's VASOTEC® tablets, will not be referred to separately in the remainder of this Brief as all statements made about the Product Monograph also apply to the *Dictionnaire Vidal*.

With the assistance of a videotape shown in open court during his testimony, Mr. McLeod provided a verbal and visual, step-by-step explanation of Merck's process. Not only was Mr. McLeod's testimony presented directly to Apotex Canada's agents (i.e., Apotex Canada's attorneys) in the courtroom that day, but it was also available to Dr. Sherman (Apotex Canada's president in 1994), Apotex Canada's other employees and experts, the rest of the pharmaceutical industry and to the general public because neither the testimony nor the videotape was subject to any protective order or confidentiality restrictions. Pet. App. A, 3a-4a; Pet. App. B, 35a.

It was not and could not be disputed that:

- As early as October 19, 1992, the Product Monograph publicly disclosed that "[i]n addition to the active ingredient, enalapril maleate, each tablet contains non-medicinal ingredients including iron oxides, lactose, magnesium stearate, sodium bicarbonate and starch." Product Monograph attached in Joint Appendix to Federal Circuit Appeal, A165; Pet. App. B, 26a.

- On March 28, 1994, Mr. McLeod publicly testified:

  - Disclosing Merck's process for manufacturing VASOTEC® tablets. He described the "steps that [Merck] follow[s] in taking the active ingredient from enalapril maleate into a final dosage form." *See* McLeod Canadian Tr. Tran. attached in Joint Appendix to Fed. Cir. Appeal, at A1006, lines 10-14; *see also* Pet. App. A, 3a, 16a; Pet. App. B. 25a-26a, 35a.

- That the ingredients of VASOTEC®, other than the lubricant (magnesium stearate), are mixed in a planetary mixer. McLeod Canadian Tr. Tran. attached in Joint Appendix to Fed. Cir. Appeal, at A1007, lines 10-25, A1010, lines 15-20. This was demonstrated in the videotape that was shown contemporaneously with the testimony. McLeod Canadian Tr. Tran. attached in Joint Appendix to Fed. Cir. Appeal, at A1007-A1010.

- That water is added to the mixture of the ingredients to create a damp mass in a wet granulation step. McLeod Canadian Tr. Tran. attached in Joint Appendix to Fed. Cir. Appeal, at A1009, lines 2-13; *see also* Pet. App. B, 25a. This was demonstrated in the videotape that was shown contemporaneously with the testimony. McLeod Canadian Tr. Tran. attached in Joint Appendix to Fed. Cir. Appeal, at A1009, lines 12-13.

- That the damp mass is dried by spreading it on trays and baking it in a drying oven. McLeod Canadian Tr. Tran. attached in Joint Appendix to Fed. Cir. Appeal, at A1009, line 24 - A1010, line 8; see also Pet. App. B, 25a-26a. This was demonstrated in the videotape that was shown contemporaneously with the testimony. McLeod Canadian Tr. Tran. attached in Joint Appendix to Fed. Cir. Appeal, at A1009, line 24 – A1010, line 8.

- That the dried ingredients are ultimately tableted (after they are blended with the

> lubricant – magnesium stearate). McLeod Canadian Tr. Tran. attached in Joint Appendix to Fed. Cir. Appeal, at A1010, lines 15-20; *see also* Pet. App. B, 26a. This was demonstrated in the videotape that was shown contemporaneously with the testimony. McLeod Canadian Tr. Tran. attached in Joint Appendix to Fed. Cir. Appeal at A1010, line 10-A1011, line 7.

- Merck disclosed the ingredients used in manufacturing VASOTEC® tablets in the 1988 edition of Dictionaire Vidal. Pet. App. A, 3a, 16a.

Dr. Sherman admitted that, given Merck's disclosure of the ingredients (specifically enalapril maleate and sodium bicarbonate) and their mixing in a wet granulation process with water, the occurrence of the acid-base reaction was obvious. Dr. Sherman made this admission in a statement that he prepared in connection with the 1994 trial in the Canadian litigation setting out the evidence that he intended to introduce with respect to his understanding of Merck's process. The courts below recognized this admission. Pet. App. C, 41a-42a; Pet. App. A, 16a-17a. In particular, Dr. Sherman stated that:

> Since enalapril maleate has acidic functional groups, it is obvious to any knowledgeable [sic] formulator or chemist that, when enalapril maleate and sodium bicarbonate are mixed and wetted [in a wet granulation], there will be an acid-base reaction. Dr. Sherman's VASOTEC Tablets Statement of Facts attached in Joint Appendix to Fed. Cir. at A1096 at ¶ 7.

Thus, Apotex USA's own chairman and named inventor has admitted that Merck's disclosure informed anyone knowledgeable in this field, which includes anyone at Apotex Canada, of Merck's formulation process to make VASOTEC® tablets. Apotex USA Admissions attached in Joint Appendix to Fed. Cir. at A1096 at ¶ 21. The courts below so concluded. Pet. App. B, 37a; Pet. App. A, 16a-17a.

The indisputable facts could not have made this case any clearer. Merck directly disclosed its process to Apotex USA and to Dr. Sherman, who then sought and received the patents to Merck's process. Apotex USA has argued and reargued its theory that Merck's disclosure was not proper. The petition for certiorari presents no compelling reasons for its grant, and is nothing more than a desperate attempt to avoid the finality of the Federal Circuit's decision.

REASONS FOR DENYING THE PETITION

This is a case in which Merck scientists were the undisputed first inventors of the accused process. Merck discovered the process and has practiced it since 1983. In the context of a Canadian litigation, Merck presented its process to Dr. Sherman and the Canadian affiliate of Apotex USA in 1994 without any confidentiality restrictions. Shortly after this disclosure and having lost the Canadian litigation, Dr. Sherman applied for the now invalidated patents, assigned them to Apotex USA, and, on the day of their issuance, sued Merck for practicing its own method.

The courts below examined the undisputed facts, including the opinion by the Canadian court, and concluded that, at the very least, as of the time that Dr. Sherman made his alleged invention, Merck was not suppressing or concealing its prior art process. Since this predated the earliest possible conception date by Dr. Sherman, the courts

ruled that Apotex USA was not entitled to valid patents that would cover Merck's process.

Thus, Merck presented an undisputed and clear-cut case of first inventorship. And, simply put, the courts below properly concluded that no reasonable person could decide that Merck was concealing its previously discovered process while at the same time it was openly disclosing it to its competitor, Dr. Sherman.

"Review on a writ of certiorari is not a matter of right, but of judicial discretion. A petition for a writ of certiorari will be granted only for compelling reasons." Sup. Ct. R. 10. The petition falls far short of providing compelling reasons for granting a writ. The petition: fails to raise any issue of first impression, argues an issue waived at previous stages in the case, relies upon an inapplicable statute, and simply takes issue with the particular result that the United States District Court for the Northern District of Illinois reached in a particular case and the Federal Circuit's decisions to affirm the district court decision. This brief addresses Apotex USA's arguments in the order in which Apotex USA presents them in its petition.

I. The Petition Does Not Raise A Question Of Special Importance With Regard To "Multi-National Drug Companies' Participation In The Patent Systems Of Different Countries."

Apotex USA has raised nothing more in its petition than a disagreement with: the district court's conclusion that no genuine issues of material fact existed; the district court's application of the law to the facts; the district court's reconsideration of its decision; and the Federal Circuit's decisions, on two occasions, to uphold the decision of the district court. While Apotex USA takes great issue with each

of these decisions, they are nevertheless decisions on a particular issue, concerning a particular patent and particular prior art and are based upon a record containing all of the relevant evidence. Apotex USA's attempt to wave global, current events before the Court does not transform an adverse decision on a summary judgment motion into an issue of international importance, much less an issue justifying a grant of certiorari by this Court.

Merck has disputed vehemently and continues to dispute Apotex USA's contention that Merck's position in the present litigation is in any way contrary to the position Merck took in previous litigation in Canada. Both the district court and the Federal Circuit have agreed with Merck. But even if, for argument's sake, Merck's present position were contrary to its position in the previous Canadian litigation (which it is not), Apotex USA has made no showing that such an inconsistency should implicate this Court's powers to grant certiorari. *See* section III.A., *infra*.

II. The Petition Does Not Present Any Important Questions Of Federal Law Yet Undecided By This Court, But, Rather, Presents Flawed Arguments Based On Misstatements Of Fact And Law.

A. Merck Did Not Need to Prove That the Evidence Negating Suppression and Concealment Was Known to People in the United States

Apotex USA attempts to conjure up an issue of first impression for this Court by misconstruing section 102(g) of the patent statute and the decisions of the district court and Federal Circuit. In pertinent part, section 102(g) provides that: "[a] person shall be entitled to a patent unless – ... (2) before such person's invention thereof, the invention was

made in this country by another inventor who had not abandoned, suppressed, or concealed it." The case law has held that a previous invention that was abandoned, suppressed, or concealed will, nevertheless, constitute invalidating prior art if the abandonment, suppression or concealment is negated before the second inventor "invents" the patented invention. *See* Pet. App. 15a-16a; *Paulik v. Rizkalla*, 760 F.2d 1270, 1275 (Fed. Cir. 1985).

Contrary to Apotex USA's argument, neither section 102(g) nor the case law places any requirement whatsoever on one challenging a patent based upon section 102(g) prior art to prove by clear and convincing evidence that anyone in the United States had actual knowledge of the acts negating suppression or concealment. The case law has succinctly set out that publication is not a prerequisite for the lack of suppression or concealment. *Oddzon Products, Inc. v. Just Toys, Inc.*, 122 F.3d 1396, 1401-03 (Fed. Cir. 1997). For example, the Federal Circuit stated in *Oddzon* that the lack of suppression or concealment is not synonymous with an affirmative duty to make a prior invention public:

> [S]ubsection (g) relates to prior inventions of others that are either public **or** will likely become public in the sense that they have not been abandoned, suppressed, or concealed.

Id. at 1402 (emphasis added). The *Oddzon* opinion in discussing the 1984 amendments to 35 U.S.C. section 103 again reaffirmed that "an earlier invention which is not public may be treated under Section 102(g) ... as prior art." *Id.* at 1403 (citing Section-by-Section Analysis: Patent Law Amendments Act of 1984, 130 Cong. Rec. 28069, 28071 (Oct. 1, 1984), *reprinted in* 1984 U.S.C.C.A.N. 5827, 5833. That the second inventor need not have access to a prior invention and that it does not even need to be "known in the

art" was also expressly set out in *Du Pont v. Phillips Petroleum Co.*, 849 F.2d 1430 (Fed. Cir. 1988), where the Federal Circuit specifically sanctioned the "secret nature" of section 102(g) prior art:

> [T]he requirement of proving no abandonment, suppression or concealment does mollify somewhat the "secret" nature of § 102(g) prior art.

Id. at 1437. Therefore, Apotex USA's contention that Merck had to prove that any disclosure it made reached the public is contrary to the law.

In granting summary judgment that Apotex USA's patents were invalid based upon Merck's previous invention, the district court explained:

> By its plain language, the statute [(section 102(g))] requires only that the [prior art] process is invented in the United States, not that the process be employed or disclosed in the United States after being invented. *See also Paulik v. Rizkalla*, 760 F.2d 1270, 1278 (Fed. Cir. 1985)(Rich, J., concurring). Judge Rich, who was intimately involved in drafting § 102(g), explained that one of the earlier versions of the statute required more of the inventor's activities to occur in the United States; specifically, it required that the prior invention be "made in this country by another who had not abandoned it and who was using reasonable diligence in this country in reducing it to practice...." *Paulik*, 760 F.2d at 1278 (Rich, J., concurring). ***That language was taken out in favor of the current version,***

> ***which requires only that the invention be made in this country and not abandoned, suppressed or concealed in any country.*** *Id.* The undisputed record evidence shows that Merck's scientists invented the accused process and reduced it to practice at Merck's lab in West Point, Pennsylvania.

Pet. App. B, 31a (emphasis added). This statement of the law was well reasoned and soundly based upon both the history of the statute and the case law interpreting it.

In its decision on Apotex USA's motion for reconsideration, the district court further explained:

> [a]t the hearing on Apotex's motion to reconsider, Merck argued that § 102(g) does not require disclosure of the invention to the public; it simply requires that the invention is neither concealed nor suppressed. The Court quite agrees and tried to make this point clear in its January 20 opinion. *See Apotex Corp.*, 2000 U.S. Dist. LEXIS 641, No. 96 C 7375, 2000 WL 97582, at *8. *See also E.I. DuPont*, 849 F.2d at 1437 ("Nor does § 102(g) contain a 'known to the art' requirement apart from the requirement of no abandonment, suppression or concealment.") Thus, whether Merck made its invention "known to the art" or publicly known is immaterial as long as Merck did not otherwise suppress or conceal its invention. As explained above and in the Court's earlier opinion, it did not.

Pet. App. C, 45a](noting that Apotex USA's own exhibits demonstrated that at least one member of the public was

present in court when Merck's expert described Merck's process). Thus, the Court explained not only that Apotex USA's argument was contrary to Federal Circuit precedent, but that, even under the rule urged by Apotex USA, Merck would have satisfied the rule.

The Federal Circuit agreed that acts negating suppression or concealment need not occur within the United States:

> As an initial matter, we disagree with Apotex's interpretation of § 102(g) as requiring proof negating suppression or concealment to arise from activities occurring within the United States. The plain language of § 102(g) clearly requires that the prior invention be made "in this country." However, in light of the grammatical structure of § 102(g), it would be a strained reading of that provision to interpret the language "in this country" to also modify the requirement that the prior invention was "not ...abandoned, suppressed, or concealed." A more reasonable interpretation is that it only modifies the antecedent verb "made," but not the "abandoned, suppressed, or concealed" clause that follows it. Had Congress intended the phrase "in this country" to modify "abandoned, suppressed, or concealed," it would have inserted language to that effect.
>
> Indeed, if there were any doubt, the legislative history of § 102(g) demonstrates that Congress contemplated that precise

> modification, as it applied to another clause in § 102(g), and failed to adopt it.

Pet. App. A, 7a-8a. If the negating act need not have occurred in the United States, then where would the legal basis be for requiring Merck to show that someone in the U.S. had knowledge of negating acts abroad? The answer is that no such basis exists, and Apotex USA's argument is plainly contradicted by the language of the statute, its legislative history, and the case law. In fact, the patent statute provides for a number of other types of invalidating prior art, such as foreign patents and publications, which require no proof that anyone in the United States was aware of the art. *See* 35 U.S.C. §§102(a), (b). The bottom line is that Apotex USA attempts to create an issue of first impression by urging the Court to read an additional requirement into section 102(g) that does not exist and is in fact precluded by existing legal authority. The Federal Circuit appropriately affirmed summary judgment on the basis of Merck's disclosures abroad and Apotex USA's own admissions concerning the public availability of information about Merck's invention. Pet. App. A, 16a-17a.

B. Apotex USA's Argument Concerning Section 282 Is Inappropriate

1. Apotex USA Has Waived Any Argument It Could Have Made Concerning Merck's Compliance With Section 282

Apotex USA never raised an issue concerning Merck's compliance with 35 U.S.C. § 282 at the district court level – either in its opposition to Merck's motion for summary judgment or in its motion for reconsideration of the district court's decision on summary judgment. Likewise,

Apotex USA did not raise such an argument in its brief on appeal to the Federal Circuit or in its Combined Petition for Panel Rehearing and Rehearing En Banc. In fact, it was only after changing lead counsel, that Apotex USA attempted to raise an issue under section 282 for the first time at the Federal Circuit in its Motion for Leave to File Supplemental Authority in Further Support of Rehearing. The Federal Circuit denied that motion *sua sponte*, as inappropriate. Apotex USA cannot for the first time raise new arguments in its attempt to relitigate this case for the fifth time.

2. Even if Apotex USA's Argument Were Timely, it Does Not Raise an Important Question of Federal Law, Misses the Issue, and is Simply Disagreement with the District Court's Factual Findings and Legal Conclusions in a Particular Instance

Apotex USA's argument is case specific – Apotex USA argues that Merck's identification of its own prior invention and use of the very process that Apotex USA accused of infringement was inadequate ***in this particular case*** to satisfy a statute designed to give an opponent thirty days' notice of evidence in advance of a trial. The Petition blatantly misstates the law at page 6, when it describes pretrial disclosure under section 282 as a requirement for asserting a defense in a case at all. *See* 35 U.S.C. § 282. Since the district court invalidated Apotex USA's patents on summary judgment, and not at trial, Section 282's requirement concerning the identification of evidence "at trial" was simply inapplicable to the case at hand.

Apotex USA's argument also misses the mark because the purpose of Section 282 is to give a patent holder notice so that it may respond to evidence supporting a

validity challenge at trial and avoid trial by ambush. In the case at hand, there can be no doubt whatsoever that Apotex USA had full knowledge of the prior art upon which Merck relied for its challenge to the validity of Apotex USA's patents. In other words, this prior art was the very Merck process that Apotex USA accused of infringement and that Merck had practiced before Apotex USA claimed to have invented it. Apotex USA agreed that Merck had used the process previously, and the district court so concluded. Pet. App. B, 29a-30a, 34a. Moreover, to the extent that Apotex USA thought that it needed additional information concerning Merck's section 102(g) defense, Apotex could have filed a motion under rule 56(f) of the Federal Rules of Civil Procedure, but never did so. Finally, section 282 provides that "[i]n the absence of such [pretrial] notice proof of the said matters may not be made at the trial except on such terms as the court requires." Thus, even at trial, according to section 282, a trial court has the discretion to set the terms for proof of prior art defenses.

The primary issue decided by the district court and reviewed by the Federal Circuit was whether Merck acted so as to negate any suppression or concealment of its previous invention of the formulation process at issue. Merck set forth fully in its motion for summary judgment the "negating" acts and provided evidence of those acts. In response, Apotex USA never raised with the district court that it needed any additional information or that it believed that it did not receive any information that may have been useful in its response to Merck's summary judgment motion. Accordingly, section 282 was irrelevant to the district court's decision on summary judgment.

In any event, Apotex USA's contrived argument concerning section 282 does not raise an important question of federal law.

III. The Petitioner Takes Issue With the Lower Courts' Determination that No Genuine Issues of Material Fact Existed and the Application of Properly Stated Rules of Law, Neither of Which Warrants Exercise of This Court's Powers

Apotex USA's petition is loaded with accusations of deception and fraud on the patent system and the judiciary, in hopes of painting a picture of the judicial system running so grossly awry that the Supreme Court should issue a writ of certiorari. Merck obviously disagrees with Apotex USA's allegations, and, in accordance with Supreme Court Rule 15.2, to the extent not stated elsewhere in this opposition brief, Merck has outlined its disputes with Apotex USA's statements of the facts elsewhere in this brief.

No matter how Apotex USA attempts to spin the facts and the law, Apotex USA's argument that the Federal Circuit has sanctioned a departure from the accepted and usual course of judicial proceedings boils down to nothing more than what many petitioners undoubtedly present and what the Rules of the Supreme Court state are rarely the grounds for a writ of certiorari – a dispute with determinations about fact issues and the courts' application of properly stated rules of law.

A. The Federal Circuit Did Not Unacceptably Depart from the Usual Course of Judicial Proceedings

Apotex USA's argument that the district court's summary judgment conflicted with the Canadian court decision is blatantly false. *See* Pet. App. B, 34a-36a. The same issues were not before the Canadian court in that case, and the district court did not reach a decision contrary to that of the Canadian court.

Even if the district court's decision had conflicted with that of the Canadian court, Apotex USA has not shown how such a decision could justify this Court issuing a writ of certiorari. Contrary to Apotex USA's assertion, *Aetna Ins. Co. v. United Fruit Co.*, 304 U.S. 430 (1938) does not stand for the proposition that conflict between a district court decision and the decision of a foreign court is a reason for granting certiorari. *Aetna* is a case involving maritime law. This Court explained that, at the time of *Aetna*, U.S. jurisprudence looked to the jurisprudence of England for principles of maritime insurance law. *Id.* at 438. ("We recognize that established doctrines of English maritime law are to be accorded respect here...."). The Court granted certiorari in *Aetna* because it believed that a decision by the Second Circuit conflicted with the law applied by English courts in previous cases between completely different parties than those involved in the *Aetna* case. *Id.* at 434, 438. Ultimately, this Court affirmed the decision of the Second Circuit in *Aetna* because the English principles of maritime insurance law in question had never been adopted by an appellate court, had been doubted by eminent judges, and conflicted with established principles of maritime insurance law. *Id* at 438-39.

Apotex USA incorrectly argues that *Aetna* is legal authority for the argument that ***if*** factual findings differ (and they do not) or ***if*** legal conclusions differ (and they do not) between those in Merck's previous litigation in Canada and those in the present case, then certiorari would be proper. In *Aetna*, the courts of the U.S. had looked to the courts of England for specific maritime law principles. That is the reason why this Court granted certiorari in *Aetna* and, contrary to Apotex USA's argument, not because it saw the Supreme Court's duty as to ensure that all decisions of U.S. courts were consistent with those of foreign courts. This Court does not sit to square its decisions with those of courts

of other countries, and Apotex USA has cited no authority that certiorari would be justified to do so.

B. The Federal Circuit Did Not Ignore Evidence Justifying Certiorari

Apotex USA's petition is replete with misrepresentations as to the facts that underlie the Federal Circuit and district court opinions. Despite Apotex USA's continuous and desperate attempts to insinuate some sinister plot, the facts have now been reviewed four times and by two courts. It is undisputed that Merck was the first inventor of the process. And no reasoned argument can be made that Merck was suppressing or concealing the process at the time that Dr. Sherman allegedly invented it after the trial at the Canadian litigation. Therefore, the patents were rightfully adjudicated invalid. *See, e.g., Paulik v. Rizkalla*, 760 F.2d 1270 (Fed. Cir. 1985) (en banc), *appeal after remand*, 796 F.2d 456 (Fed. Cir. 1986).

1. The Courts Below Considered All of the Evidence

Apotex USA's argument that the district court and Federal Circuit assumed that the present case was one of concealment inferred from delay and not a case of "intentional concealment" is nothing more than a "red herring."

Apotex USA introduces its argument through *Paulik v. Rizkalla*, 760 F.2d 1270 (Fed. Cir. 1985). Contrary to Petitioner's discussion, while *Paulik* discusses some differences in various courts' treatment of different cases of suppression and concealment based upon the reasons for the suppression or concealment, *Paulik* does not hold that intentional concealment could not be negated by subsequent

acts. *Id.* at 1275-76. Instead, *Paulik* merely holds that an earlier inventor's resumed activity may negate a previous delay in reducing an invention to practice, allowing the first inventor to obtain a patent. *Id.* In this case, the courts applied the law to the facts and reached the particular result, that any suppression or concealment that Merck had committed had been negated by Merck's subsequent acts. Pet. App. 15a-16a, 33a-36a. Apotex USA simply disagrees with the decisions of the district court and Federal Circuit, and that disagreement did does not justify certiorari.

Apotex USA also rehashes its argument that Merck did not prove by clear and convincing evidence that the public had gained knowledge of the invention, Petition at p. 25, even though the law imposes no duty to prove any public awareness. *See* Section II.A., *supra*.

Along the way, Apotex USA makes a blatantly false allegation that Merck Frosst used "fake" ingredients in its videotape exhibit (narrated at the Canadian trial by Mr. McLeod) for "no reason," implying an intent on the part of Merck Frosst to deceive. This statement was blatantly false because, as Merck brought to the attention of the Federal Circuit, McLeod clearly explained in the Canadian trial that: 1) the materials were being shown only for purposes of illustrating the process in this visual, demonstrative video exhibit; and 2) representative materials were being used in place of actual ingredients for safety reasons:

> [Merck] chose not to use the active ingredients in this particular [video] production because when we took the lights into the production area, there was a concern about safety of stability and explosion with these particular active ingredients with the

> lights. So, in fact what you are actually looking at is a placebo at this stage.

Transcript of March 28, 1994 trial testimony of Brian McLeod in *Merck & Co., Inc. et al. v. Apotex, Inc.* in the Federal Court of Canada Trial Division at pp. 123-24, which was of record and included in the Joint Appendix to the appeal to the Federal Circuit at pp. A1067-68. Apotex USA omitted the cited material from the appendix to its petition.

In addition, Apotex USA's petition confusingly alleges that other acts by Merck were misleading and somehow created a genuine issue of material fact. Petition, at pp. 25-26. To do this, Apotex USA argues that the courts below overlooked the statements of Apotex USA's personnel and experts, despite the fact that those courts considered those statements. Pet. App. C, 41a-45a; Pet. App. A, 14a-17a.

2. The Courts Have Considered the Evidence Four Times

Again, emphasizing that the district court's decision did not conflict with the previous decision of the Canadian court and that even such a discrepancy would not amount to an unacceptable departure from the usual course of judicial proceedings, Merck asserts that Apotex USA's argument that the Federal Circuit ignored evidence is unfounded and inappropriate because the issue of suppression and concealment have been considered by the courts on four separate occasions before the present petition – by the district court on summary judgment; by the district court on petition for reconsideration; by the Federal Circuit on appeal; and by the Federal Circuit on petition for panel rehearing and rehearing en banc. Apotex USA lost at each and every step along the way to this Court, and it defies rational belief to

think that the courts ignored evidence on four separate occasions. The courts below did consider all of the evidence before them and reached the appropriate conclusion, albeit a conclusion that Apotex USA does not like. Apotex USA's allegations are outlandish and fall far short of the standard for certiorari.

C. Apotex USA's Argument About The Record as a Whole is Nothing More than Disagreement with Factual Findings

Apotex USA's argument about "the record as a whole" is a final cry of desperation based on nothing more than allegations of the district court's determination of the absence of genuine issues of material. Such a determination was purely within the province of the district court and was considered by the Federal Circuit on appeal. No basis for certiorari lies in "the record as a whole."

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be denied.

Respectfully submitted,

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IN THE

Supreme Court of the United States

APOTEX USA, INC.,

Petitioner,

v.

MERCK & CO., INC.,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

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Even if it were reasonable to find the facts as Merck & Co., Inc. ("Merck") has set them out (and that would be against the weight of the evidence), that would not justify the entry of summary judgment below in the face of the evidence of intentional suppression and concealment advanced by Apotex USA, Inc. ("Apotex"). It is a fact of life that the type of pharmaceutical here at issue is an item of global commerce. When dealing with international commerce, it is an unreasonable departure from the normal course of judicial proceedings for the courts of this country to turn a blind eye to inconsistencies between a position asserted by a litigant in this country and positions on which it has prevailed in a foreign country. Certiorari is an appropriate vehicle with which to remedy this inequity.

I. Merck's Inconsistency Is One Reason To Grant Certiorari.

Merck maintains that it was not inconsistent for it first to persuade a Canadian court that no chemical reaction occurs in the process it uses, then to assert in a United States court that its earlier denial was actually a *disclosure* of that very process. That conduct by one tentacle of a multi-national drug company has implications far beyond this one case. The conduct of such companies is not only central to modern global commerce; it also impacts on basic human rights throughout the world. Our federal courts cannot simply wink at Merck's hypocrisy here. To do so undermines the constitutional purpose of our patent system, to promote the progress of the useful arts.

As acknowledged in *Aetna Ins. Co. v United Fruit Co.*, 304 US 430 (1938), conflicts with the decisions of a foreign court *can* be a proper basis for certiorari. As Merck notes on pages 21–22 of its Brief in Opposition, the particular issue in that case concerned a point of maritime law — but nothing in the decision limits it to that field. In the case at bar, the inconsistency is much more profound. Merck prevailed in persuading the Canadian court that no chemical reaction occurred in making its pharmaceutical. That chemical reaction (which Merck denied) is exactly what Apotex claimed in its U.S. patent application. Summary judgment effecting a forfeiture of Apotex's federal property right simply cannot be an

appropriate mechanism under the Federal Rules of Civil Procedure for resolving such a dispute. Certiorari should therefore be granted, the judgment below should be vacated, and the case should be remanded for further proceedings.

II. Merck Suppressed and Concealed the Invention.

A. Merck Intentionally Suppressed and Concealed

The important substantive issue of patent law in this case is not *disclosure*; it is Merck's intentional *suppression* and *concealment*. While disclosure is related to suppression and concealment, it is not the same thing or even a flip side of the same coin.

The central thing, the "it" that is the invention covered by this patent, is a chemical reaction. In the Canadian suit Merck *denied* that "it" occurred. Dr. Sherman, the inventor for Apotex, realized that Merck was not telling the truth. He knew that "it" (the chemical reaction) did occur, and he so testified in the Canadian court.

Merck, however, prevailed in its false denials in Canada. It told the big lie, and got away with it. That ill-gotten triumph in the Canadian court typified Merck's suppression and concealment before and up to that time. Faced with the conflicting evidence of (1) Dr. Sherman explaining that the reaction occurred and (2) Merck's bald-faced denial, MacKay, J., ruled:

> The difficulty encountered is said to be that including the compound enalapril maleate, here said to be the active ingredient, in both VASOTEC and APO-ENALAPRIL, with regularly accepted adjuvants, as the patent indicates, presented a major problem in assuring stability of the product and avoiding undue disintegration. Dr. Sherman, who was directly responsible for overseeing product formulation at Apotex, said that in his experience the development of a product for consumption in dosage form where the active ingredient was comparatively small

was a "no-brainer", easily accomplished. In this particular case, however, he had encountered the most difficulty of any product development in his experience. From document production by Merck, for counsel's eyes only by agreement, it was apparent that addition of one common adjuvant, sodium carbonate or sodium bicarbonate, was a part of Merck's tablet development and questions were asked in the course of discovery about this. Questions were also raised at trial, of Dr. Schwartz, an expert appearing for the plaintiffs, and Drs. Niebergall and McClelland, experts for the defendant. *The questions sought confirmation that the Merck process of tablet formulation may well have been inventive in the manner of its resolution of the problem of disintegration, by producing a reaction through use of sodium carbonate or bicarbonate, and water, that solved the stability problem but left something other than enalapril maleate as the active ingredient. None of the experts could confirm this was the inevitable result of the information provided to them, though all confirmed that depending upon the process of mixing and the relative volume of water mixed, a reaction could be expected.*

Merck & Co. Inc. v. Apotex Inc., No. T-2408-91, 59 C.P.R. (3d) 133, 181, 1994 C.P.R. LEXIS 2122, *113–*115 (Fed. Ct., Dec. 14, 1994), *reprinted at* L58 (emphasis added).

This statement by Judge MacKay is even more than a finding of suppression and concealment — it is the actual fruits of that suppression and concealment itself. Merck's deception of Judge MacKay (about the reaction that did in fact occur) helped it to prevail in the Canadian litigation.

Apotex adduced more than enough evidence in affidavits to raise a genuine issue as to the material fact of suppression and concealment. One expert, Dr. Scheindlin, specifically stated in his declaration, "Mr. McLeod's use of the word 'stabilizer' in his 1994 testimony *is deceptive*. Sodium bicarbonate does not act as a stabilizer *per se*, but rather is an important ingredient of a chemical reaction to convert enalapril maleate to enalapril sodium."

(emphasis added). Similarly, a declaration from Dr. Sherman established that McLeod's testimony *concealed* that the water being added would produce a chemical reaction, and thus *suppressed* the aspect of the process that the Apotex patent identifies as a critical improvement over the prior art.

The clincher showing Merck's suppression and concealment is its own internal document admitting its motive for its deception. Merck admitted, "[W]e have a major concern regarding the presence of a statement on the product label which infers the formation of a sodium salt of enalapril maleate. *Such a statement might affect worldwide registration of the product and existing approved labeling.*" The "formation of a sodium salt of enalapril maleate" is the chemical reaction that is the "it" of the invention in suit. That is exactly the reaction that Merck could not afford to admit, because it would jeopardize "worldwide registration of the product and existing approved labeling." In fact, and despite the arguments in its brief implying the contrary, Merck did *not* disclose that critical fact.

B. Merck's Alleged Disclosures Did *Not* Disclose the *Invention*.

Merck did *not* disclose at all the *true* process it used to manufacture its drug, either in the Canadian litigation or before. In the true process that Merck actually uses, during the course of mixing the ingredients with water, a reaction is caused between enalapril maleate and sodium bicarbonate to convert the enalapril maleate to enalapril sodium.

During the Canadian trial and before, Merck made *no* disclosure *whatsoever* of this reaction. Instead, Merck suppressed and concealed the crucial fact: that this reaction occurred. Before the Canadian trial, Merck had concealed this information by incomplete, inaccurate, false, and misleading submissions to regulatory authorities such as the Food and Drug Administration. During the trial, it concealed that fact even from its own paid expert witness, Dr. Schwartz.

Merck's VASOTEC tablets are falsely labeled as containing enalapril maleate when, in fact, they contain enalapril sodium. Contrary to Merck's assertions in the courts below, the label on a pharmaceutical is not meant to list the starting ingredients in a process. Instead, it is supposed to list the *results* of any reaction, identifying exactly what is in the tablet being put in to the patient's body. Apotex established this fact below with declarations submitted in opposition to Merck's summary judgment motion. If Merck were correct (it is not), and if a pharmaceutical label were meant to identify starting ingredients (it is not), then Merck's label would nonetheless be deficient because that label does not identify all of the critical ingredients such as, for example, water. The omission of such a critical starting ingredient is further evidence showing that the pharmaceutical label was supposed to list not the starting ingredients, but instead the *results* of any reaction to identify the actual ingredients comprising the tablet a patient will ingest.

III. Dr. Sherman's Inventive Insight Does Not Negate Merck's Suppression and Concealment.

Dr. Sherman, Chairman of Apotex, is an expert in pharmaceutical formulation and has received patents for numerous inventions. Yet even Dr. Sherman, who has more than ordinary skill in this art, was deceived for several years by Merck's mislabeling of its drug. Dr. Sherman had tried to replicate Merck's tablets, but found that tablets he made containing enalapril maleate (not as a starting ingredient but instead, as listed on Merck's label, as part of the final tablet) were unstable. When Dr. Sherman learned more details about Merck's initial ingredients, he knew that its product labeling was false. He independently invented the process of causing the critical reaction. Merck, however, continued to *deny* that any such reaction occurred.

During the Canadian litigation it was Dr. Sherman, and not Merck, who disclosed that a reaction must be occurring. This point is critical. *Dr. Sherman made the only disclosure of a reaction, which disclosure* a fortiori *must have occurred after Dr. Sherman came up with the invention himself.* There was no disclosure by Merck of any reaction, and no disclosure of that reaction by anyone

before Dr. Sherman independently invented it and so testified in the Canadian proceedings.

One of Apotex's attacks upon Merck's Canadian patent was that it failed to disclose that a reaction was needed in order to get a stable tablet. Not only did Merck fail to disclose and refuse to admit that there was a reaction and that the tablets contained enalapril sodium and not enalapril maleate, but also Merck's own experts on cross-examination refused to admit that conversion to enalapril sodium necessarily occurred. Assuming that Merck's expert in the Canadian litigation testified truthfully, his testimony merely proves that Merck *concealed the fact that a reaction occurred even from its own paid expert.*

IV. Apotex Did Not Waive Its Arguments under § 282, Which Are Applicable Here.

Apotex's invocation of § 282 was not a new argument in the Federal Circuit and is not a new argument here. Apotex sought in the District Court to have Merck identify the individual whom it alleges invented the process at issue. That identification, which Apotex timely sought in the District Court, is exactly what § 282 requires.

Merck's argument that § 282 is applicable only at trial and not on summary judgment would lead to the anomalous result that a case could be decided in the posture of summary judgment based on evidence that could not be presented at trial. That is not the law. While evidence submitted in response to a summary judgment motion need not be in the *form* at which it would be adduced at trial,[1] that evidence still must be such that it would be *admissible* at trial. The entire point of the summary judgment procedure is to determine whether there exists a genuine issue for trial. The question is whether a jury could properly find in favor of the non-movant. A trial cannot be avoided on the basis of evidence that a party could not present.

---

[1]For example, witness testimony may be offered by affidavit or declaration instead of direct examination and cross.

Merck suggests on page 19 of its Reply that this case is somehow special because the allegedly prior invention is the same process accused of infringement. Contrary to Merck's implication, that circumstance is not unusual. It is typical. It is exactly what § 282 was intended to address.

Finally, Merck asserts that the application of § 282 is within the discretion of the District Court. While that may be, here there is no indication on the record that the District Court purported to exercise such discretion. Instead, it simply ignored this statutory requirement.

V. Merck's Disclosures that Never Reached the United States Are Not Sufficient To Negate Its Suppression and Concealment.

Cases that Apotex cited in its petition interpret § 102(g) as requiring that the alleged prior inventor (Merck) prove that the public has gained knowledge of the invention. *Palmer v. Dudzik*, 481 F.2d 1377, 1387 (C.C.P.A. 1973). As explained in Apotex's petition, that interpretation is necessary to effectuate the Constitutional purpose of the patent laws.

This Court has explained the Constitutional standard authorizing and limiting the U.S. patent laws as follows:

> At the outset it must be remembered that the federal patent power stems from a specific constitutional provision which authorizes the Congress "To promote the Progress of ... useful Arts, by securing for limited Times to ... Inventors the exclusive Right to their ... Discoveries." Art. I, § 8, cl. 8. The clause is both a grant of power and a limitation. This qualified authority, unlike the power often exercised in the sixteenth and seventeenth centuries by the English Crown, is limited to the promotion of advances in the "useful arts." It was written against the backdrop of the practices — eventually curtailed by the Statute of Monopolies — of the Crown in granting monopolies to court favorites in goods or businesses which had long before been enjoyed by the public. *See* MEINHARDT, INVENTIONS, PATENTS AND

> MONOPOLY, pp. 30–35 (London, 1946). The Congress in the exercise of the patent power may not overreach the restraints imposed by the stated constitutional purpose. Nor may it enlarge the patent monopoly without regard to the innovation, advancement or social benefit gained thereby. Moreover, Congress may not authorize the issuance of patents whose effects are to remove existent knowledge from the public domain, or to restrict free access to materials already available. Innovation, advancement, and things which add to the sum of useful knowledge are inherent requisites in a patent system which by constitutional command must "promote the Progress of ... useful Arts." This is the *standard* expressed in the Constitution and it may not be ignored. And it is in this light that patent validity "requires reference to a standard written into the Constitution." *A. & P. Tea Co. v. Supermarket Corp.*, *supra*, at 154 (concurring opinion).

Graham v. John Deere Co., 383 U.S. 1, 5–6 (1966) (footnote omitted).

Merck asserts that, under its interpretation of the statute, the alleged prior inventor need not prove (in order to negate its suppression and concealment) that anyone in the United States public actually possessed the information. Merck does not explain how to reconcile its interpretation (which inhibits progress of the useful arts by encouraging suppression and concealment until one suspects that others may be getting close) with the Constitutional *standard* set forth in *Graham*. The "plain text" of such a statute cannot overcome the requirements of the Constitution.

But even if Merck's interpretation were consistent with that standard (it is not), Merck's proposed rule has nothing to do with the facts of this case. Not only did the United States public here not have possession of the alleged prior invention, *there was no reasonable chance of that information getting to the United States*. The counterexamples Merck suggests, of foreign patents and the like, are inapposite. A foreign patent is, presumptively, readily available to the United States public. The misleading testimony of

Merck's witness narrating a silent video in a Canadian courtroom is in no such sense accessible. Accordingly, Merck (as the party that was found to have suppressed and concealed its invention) should be required to prove that its subsequent acts negating suppression and concealment were at least such that it might have been reasonably possible for the United States public to gain the benefit of those disclosures.

VI. Merck's Reliance on What It Calls Factual Findings Begs the Question of Why the Courts Below Were Making Findings on Summary Judgment in the First Place.

A recurring theme of Merck's Brief in Opposition is that the courts below looked at all the evidence and found the facts adversely to Apotex.

That is the point.

This case was submitted on motion for summary judgment. The lower courts here were not supposed to be weighing evidence. They were not supposed to be finding facts. Instead, at this juncture, all factual issues should have been resolved in Apotex's favor. They were not.

CONCLUSION

Patents for inventions are a critical aspect of the pharmaceutical industry, which is increasingly characterized by the global conduct of multinational corporations. This case is simply about the fact that such a multi-national company should not be permitted to suppress and conceal an invention up until and including a trial in a foreign court, then (when another inventor nevertheless discovers the advance) invalidate that inventor's patent. Even if Merck did develop this process first, Apotex deserved its patent for Dr. Sherman's invention because all the way through the trial in Canada Merck continued to suppress and conceal the hidden chemical reaction that is the subject matter Dr. Sherman invented and Apotex patented. Merck mislabeled its product, withheld information about the reaction even from its own expert witness in Canada, and convinced the Canadian court that no

reaction necessarily occurred. To allow Merck then to rely on this pattern and practice of deception to negate its suppression and concealment is so far a departure from the accepted and usual course of judicial proceedings by the court of appeals and the district court as to call for an exercise of this Court's supervisory power.

Respectfully submitted

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